University of Alberta

The Effect of Dairy Products on Post-Tonsillectomy Recovery

by

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Table of Contents

Chapter 1 1

Introduction 1

Purpose of the Study 3

Hypotheses 3

Chapter 2 4

Review of the Literature 4

Diet and Tonsillectomy 5

Food Texture and Timing of Re-introduction 5

Humidity 9

Dairy Products 10

Analgesic Choice and Dosing 12

Recovery 13

Assessing Pain Post Tonsillectomy 16

Developmentally Appropriate Assessment of Pain 16

Issues Related to Pain Measurement in Children 19

Measurement Tools 23

Parent-Child Agreement on Pain Intensity 27

Pain Control Following Tonsillectomy 30

Conclusions 31

Chapter 3 33

Research Methods 33

Design....33
Setting....34
Sample and Recruitment....34
Power Analysis....35
Definition of Terms....36
Measures....37
Demographic Data....37
Food Tolerance....37
Analgesia....37
Activity Level....37
Pain Intensity....38
Complications....38
Procedures....39
Ethical Considerations and Consent....39
Instructing Parents and Children....40
Data Collection....42
Progress Monitoring....42
Data Analysis....43
Chapter 4....44
Findings....44
Sample....44
Returned Data....44
Demographics....45

Demographic 47
Dairy Group 47
Non-Dairy Group 47
Age 47
Weight 47
Gender 47
Reason for Surgery 47
Humidifier in Home 47
Season 47
Research Hypothesis One 48
Research Hypothesis Two 58
Chapter 5 62
Discussion 62
Pre-operative 64
Intra-operative 64
Post-operative 66
Post-operative Health Service Utilization 68
Defining Recovery 72
Study Limitations and Recommendations for Future Study 77
Appendix A 79
Demographic Data 79
Appendix B 80
FPS-R 80

Appendix C 81
Information Pamphlet 81
Appendix D 83
Consent Form 83
Appendix E 85
Data Table 85
Appendix F 86
Detailed Sample Size Calculations 86
Appendix G 87
Ethical Approval 87
Appendix H 88
Letter of Support 88
References 90

Tables

Table 1 Demographic Information for Dairy and Non-dairy Groups 47

Figures

Figure 1 Recovery. 49

Figure 2 Total Sample Recovery By Day 10. 49

Figure 3 Acetaminophen Usage. 51

Figure 4 Group Pain Ratings. 52

Figure 5 Dairy Group Pain Ratings. 54

Figure 6 Non-dairy Group Pain Ratings. 54

Figure 7 Toleration of Soft Diet. 55

Figure 8 Activity Level. 57

Figure 9 Day Dairy Started. 58

Figure 10 Dairy Group Complications. 59

Figure 11 Non-Dairy Group Complications. 60

Figure 13 Tonsillectomy Pain Study Comparisons. 74

Chapter 1

Introduction

Tonsillectomy is an acceptable outpatient surgical procedure for otherwise healthy children (Letts, Davidson, Splinter & Conway, 2001). Due to the advent of same day surgery, children are no longer under the direct supervision of healthcare professionals, therefore parents are now responsible for knowing the best practice in pain management for their child. It is essential to examine variables that enhance recovery and minimize the potential for complications, such as bleeding and dehydration. One issue debated by clinicians concerns post-tonsillectomy diet, which may vary from clear fluids, to soft diet, rough diet, or the elimination of dairy products.

Post-tonsillectomy dietary recommendations vary from surgeon to surgeon and institution to institution. There is agreement on the importance of consistent and early fluid intake (Carabott, Javaheri, Keilty & Manger, 1992; Schaler & Parkin, 1987). However, no consensus exists with respect to a time frame for re-introduction of soft and rough foods (Brodsky, Radomski & Gendler, 1993; Cook, Murrant, Evans & Lavelle, 1992; Thomas, Moore & Reilley, 1995). Anecdotally, some otolaryngology surgeons find that patients encounter fewer problems when dairy products are withheld in the immediate postoperative period (C. Elliott, personal communication, November 1, 2002). However, this clinical observation remains to be tested in research.

The exact mechanism for improved recovery with dairy avoidance is unclear. Possible explanations relate primarily to the viscosity of milk and milk

substitutes. Some authors believe that milk thickens pharyngeal secretions, thereby prompting throat clearing that results in increased pain and bleeding (Schaler & Parkin, 1987; Thomas et al., 1995; Whaley & Wong, 1987). Others suggest that milk contributes to bacterial overgrowth in the pharynx leading to an increased risk of complications, such as infection, pain and bleeding (C. Elliott, personal communication, November 1, 2002).

One surgeon conducted all of the tonsillectomies in this study. His standard practice is to use electrocautery when removing tonsils, creating a burn at the operative site. A common and expected sign that normal progression of wound healing is occurring is the development of granulation tissue (Kloth and McCulloch, 2002). This typically occurs 48-72 hours after injury and provides a 'protective scab' over the tonsillar fossae. The theory underlying this study was that if food substances that cling to the recovering tonsillar fossae were withheld until the granulation tissue has formed, there might have been a reduction in the bacterial overgrowth that accompanied open wounds in the oropharnyx. By reducing bacterial contamination, through the withholding of dairy products in the first 72 hours, it was anticipated that there would be an overall reduction in recovery time and an earlier resumption of usual day-to-day activities. It was also assumed that if there were a decrease in pain experienced by the child, recovery would occur at a faster rate.

Abundant literature exists substantiating pain scales as tools for assessing post-operative pain. Other aspects of recovery such as reduction of swelling or formation of granulation tissue in the tonsillar fossae are less quantifiable.

Ultimately the reduction of pain and improved overall well-being are indicative of recovery following tonsillectomy. It therefore was reasonable to consider recovery as the primary outcome variable to evaluate the effect of dairy product restriction in post-tonsillectomy in children.

Purpose of the Study

No previous studies have examined the effect of dairy products on post-tonsillectomy recovery. The purpose of this pilot study was to explore the feasibility of a randomized controlled clinical trial that tested the effect of withholding dairy products on post-tonsillectomy recovery. Recovery was operationalized using measurement of pain, number of Acetaminophen doses consumed, length of time to tolerate a soft diet and length of time to return to independent play and/or daycare/school.

Hypotheses

1) There will be no difference in recovery time if dairy products are withheld in the immediate post-tonsillectomy period.
2) There will be no difference in the incidence of the following complications: nausea, vomiting, dehydration and secondary bleeding if dairy products are withheld in the immediate post-tonsillectomy period.

Chapter 2

Review of the Literature

Tonsillectomy is one of the most common surgeries performed in general and pediatric otolaryngology. Surgery is performed for those children with recurrent tonsillitis, greater than seven infections in a given year, five in two years, or three in three years (Bluestone & Stool, 1990) or for those children who have obstructive sleep apnea syndrome (OSAS). The operation can be performed on children as young as 2 years of age, or as old as 16 years, at which time they are considered to be adults from a clinical perspective. Despite this high frequency, debate remains surrounding the dietary management of these patients. The following review of the literature will present research findings pertaining to diet and tonsillectomy patients, as well as pediatric pain and assessment tools. The literature will be discussed with respect to clinical controversies that exist in the management of children following tonsillectomy. Gaps in research evidence to guide practice will be identified. Journal articles and otolaryngology and nursing textbooks are included in this review. Computer databases searched include MEDLINE, PUBMED and CINAHL, using the keywords "diet," "tonsillectomy," "children and pain," "pain and tonsillectomy," "recovery and tonsillectomy" and "dairy and tonsillectomy." Dietary recommendations and approaches have received very limited attention from investigators; the main focus in the tonsillectomy literature is on surgical technique and intra-operative modalities to decrease pain in the immediate postoperative period. Although a ubiquitous

procedure, it is surprising how little evidence there is to guide practice in terms of dietary recommendations.

The review of the literature revealed several potential key factors regarding diet and post-operative tonsillectomy patients. These included: a) food texture and timing of re-introduction, b) dairy products, c) humidity, d) analgesic choice and dosing and e) recovery.

Diet and Tonsillectomy

Food Texture and Timing of Re-introduction

The texture of foods that are re-introduced post-tonsillectomy can be grouped into liquid, soft or rough textures. Nursing and otolaryngology authors have varied suggestions for post-tonsillectomy diet instructions. Whaley and Wong (1997) recommended that food and fluids are restricted until there are no signs of haemorrhage. However, the authors did not provide the time frame for monitoring. They recommended beginning with cool water, followed by flavoured ice pops or diluted juices once the child is alert and free of bleeding. On the first or second postoperative day, or as the child is tolerating feeding, soft foods may be re-introduced. Otolaryngologists Schaler and Parkin (1987) recommended that clear liquids be encouraged to meet maintenance fluid requirements and a regular diet be resumed on postoperative day 3-5. They advised that fruits, acidic vegetables and chocolate be avoided as they can cause discomfort. These authors also noted that many clinicians would recommend a soft diet for varying periods to minimize pharyngeal trauma.

Children under the care of one of the pediatric otolaryngologists (Elliott) at Stollery Children's Hospital are instructed to consume 100% fluid maintenance in a 24-hour period, for a 3-week period, starting in the immediate post-operative period. Fluid maintenance was calculated based on the child's weight in kilograms. Soft foods were allowed on post-operative day one; these included: popsicles, ice slush drinks, warm soup, cooked cereals, scrambled eggs, pastas and mashed potatoes (made without dairy products). Elliott recommended that children who have undergone a tonsillectomy avoid foods such as crusts, meats, raw vegetables, spicy foods, citrus fruits, chips, peanuts and hard candies for three weeks. The continuation of fluid intake is strongly recommended as regular diet is resumed, for an average of three weeks.

There was a marked variation in dietary recommendations between pediatric facilities. These variations can be illustrated through examples from websites of leading pediatric hospitals across the United States. Texas Children's Hospital post-operative instructions (2002) suggested avoiding acidic or citrus products because they may burn the throat. Cool or warm liquids and solid foods were acceptable right after surgery. Crispy or brittle foods should be avoided until healing is complete. Cincinnati Children's Hospital post-operative instructions (2002) placed no limits on what children can eat post-operatively and stated that you cannot damage the throat by giving any particular type of food. This variation in post-operative dietary recommendations is a reflection of the lack of sound research evidence from which to base clinical decisions. To date only a few studies have begun to address this empirical gap.

Two studies by Brodsky and colleagues examined the effect of post-operative diets on recovery, during various post-operative time periods. Brodsky et al. (1993) investigated the first 7-10 days post-tonsillectomy among a sample of 92 children, between the ages of 3 and 14 years. Children were assigned randomly to conditions in which they received either "restricted orders" of only liquids and soft foods for the first 7 to 10 days or "non-restricted orders" to resume a regular diet as tolerated by the patient. In the second study, Hall and Brodsky (1995) observed 100 children, ages 3-17 years for the first 12 hours post-tonsillectomy. The children were randomly assigned to two groups: non-restricted diet and restricted diet. In both studies, the non-restricted diet consisted of foods usually offered on the hospital menu, whereas the restricted diet consisted solely of full liquids and soft foods. Neither of these studies found an association between healing and dietary intake.

Cook et al. (1992) conducted a randomized comparison of three post-tonsillectomy diets in 137 adults, ages 16-56 years, to determine if post-tonsillectomy dietary advice had any effect on recovery. The diets studied were: 1) mainly rough food, 2) mainly soft food and 3) no advice except to eat regularly. Unfortunately, because the investigators did not specify exactly when the diets were introduced; their conclusions that there were no significant differences were premature. The authors mentioned a case of secondary haemorrhage related to poor dietary intake, overlooking aspirin intake in their patients and instead fault strict dietary regimens as the cause.

Thomas et al. (1995) examined children's preferences for two post-tonsillectomy diets in the immediate 24-hour postoperative period. Dietary intake was recorded in two separate phases for 50 healthy children who had undergone a tonsillectomy and adenoidectomy (T&A). During the first phase, children were offered the standard post-tonsillectomy breakfast (i.e., liquids and soft and rough foods). In the second phase, children were offered liquids, soft diet and less rough food choices. Data collected during the first phase demonstrated that children preferred liquids, followed by soft foods such as cereal and eggs (Thomas et al., 1995). Rough foods were unlikely to be eaten. Data collected in the second phase again showed children had a preference for liquids and soft foods. Based on these results Thomas and colleagues recommended an unrestricted diet with emphasis on frequent intake of liquids and soft foods.

Carabott et al. (1992) examined oral intake in children following T&A. Their study was prompted by nurses' concerns that children were occasionally forced to drink, sometimes even using a syringe, post-T&A. Children either were assigned to a control group, wherein they received "forced" fluids if necessary, or to an experimental group, wherein they were allowed to choose the rate at which their liquids were consumed. The child's date of admission was used to determine group assignment. Carabott et al. (1992) found a significant difference in fluid intake between the two groups after 6 hours following transfer from the recovery room. However, at 8 hours post transfer there no longer was a statistically significant difference. Their findings suggest that if children are given sufficient time, in this case 8 hours rather than 6 hours, they would consume an adequate

amount of oral fluids voluntarily. For those children who did not meet the fluid requirements and required further monitoring, the authors still recommended that these children be forced to consume fluids orally, as restarting an intravenous (IV) line may have been "traumatic", implying that forcing fluids was not considered to be traumatic. It was not clear why the authors did not recommend maintaining the patency of the operative IV in case of poor fluid intake; their current recommendations may place children at risk of aspiration when fluids were forcibly administered by syringe.

Of note, one study examined the feasibility, safety and efficacy of IV home hydration in a nonramdomized control trial involving two groups of children post-tonsillectomy (Park & Kim, 2002). One group received home IV hydration once a day for three days, while the other group did not. Interestingly, the hydration group had significantly more difficulty swallowing and lower activity levels than the non-hydrated group ($p < 0.05$). The reader questions if the results could be duplicated based on a randomized control trial.

The one consistent point in the literature on post-tonsillectomy diet was that adequate fluid intake be maintained from the immediate postoperative period throughout recovery. In the few studies that do exist, no significant association between texture of the food and recovery was reported. However, clinical observations in Edmonton, Alberta suggest that texture does affect recovery.

Humidity

The inconsistency between observations and research evidence may be explained by atmospheric humidity. Edmonton, the city for this research study,

has a very dry climate, particularly in the winter months. This dryness is potentially problematic for children recovering post-tonsillectomy, especially if they were unable to drink enough fluids to keep the surgical site moist. Children who were not adequately hydrated, either as a result of insufficient fluid intake or inadequate humidification at the tonsillar fossae, were at greater clinical risk of secondary haemorrhage (C. Elliott, personal communication, November 1, 2002). It was difficult to apply published findings regarding diet post-tonsillectomy to the Edmonton population, as most of the studies were done in more humid centres.

Dairy Products

Despite a thorough review of the tonsillectomy and diet literature, no single study was found that addressed the effect of dairy on the healing tonsillar fossae. Only textbooks and hospital websites provided any information on the consumption of dairy products post-tonsillectomy. Leading pediatric centres varied on the mention of dairy products allowed post-tonsillectomy. Schaler and Parkin (1987) recommend that dairy products be avoided in the immediate tonsillectomy period. Schaler et al. (1987) claimed that dairy products produced mucous in some patients and may complicate swallowing. Texas Children's Hospital (2002) allowed the consumption of dairy products in the post-tonsillectomy period, whereas Cincinnati Children's Hospital and Children's Hospital of Philadelphia (2002) made no direct reference to dairy product use. Neither the study conducted by Brodsky et al. (1993) or by Hall and Brodsky (1995), nor Cook et al. (1992) mentioned whether or not dairy products were

included in their randomized post-tonsillectomy diets. Thomas et al. (1995) were the only investigators who directly mentioned dairy products; milk was included in both phases of their study. In her study of oral fluid intake, Carabott et al. (1992) only mentioned the intake of clear fluids, suggesting that dairy products were not allowed in the immediate 8-hour post-operative period.

The relationship between milk and mucus production was addressed in the literature. Arney and Pinnock (1993) examined the "milk-mucous effect" by interviewing a total of 169 believers (those who believed that milk produced mucus) and non-believers (those who believed that milk did not produce mucus). Respondents stated that the site predominantly affected after milk consumption was the throat, with sensations related to difficulty in swallowing and perceived thickness of mucus and salivary secretions, rather than excessive mucus production. Data from the interviews revealed that the milk-mucus believers were different from non-believers, reporting more respiratory symptoms associated with the consumption of dairy and therefore consumed less milk and dairy products. The same team, Pinnock and Arney (1993), developed a questionnaire directed at the measurement of the "milk-mucous effect" after drinking milk and soy products. The authors found that common complaints after consumption included: a coating or lining over the mouth, throat or tongue (39% increase), the need to swallow a lot (31% increase) and that saliva had a tendency to be thicker and harder to swallow than before (42% increase). The question of whether dairy consumption helped or hindered the post-tonsillectomy recovery process has yet to be addressed.

Analgesic Choice and Dosing

Similar to information regarding dairy products, there were no published studies or clinical guidelines for analgesic choice and dosing post-tonsillectomy. Textbooks and websites were the only sources of information available. A review of tonsillectomy websites and otolaryngology and pediatric textbooks suggested that the post-operative analgesic of choice as acetaminophen, with or without codeine. The recommended dosing and duration of analgesic therapy was less clear. Schaler and Parkin (1987) stated that pain medications were to be given in a timely fashion. However, no analgesic reference, dosing requirements or duration were mentioned. Leading pediatric centres were consistent in the recommendation that acetaminophen be given for a period of up to two weeks post-operative and that the child should avoid products containing ibuprofen or aspirin due to the potential for secondary bleeding. Cincinnati Children's (2002) and Elliott (2002) both noted that appropriate dosing is dependent on the child's weight, while the Children's Hospital of Philadelphia (2002) stated only that the child should take pain medication as prescribed, without recommended analgesic choice, duration or dose. Brodsky et al. (1993) and Hall and Brodsky (1995) documented the daily number of doses of acetaminophen that the child received, but did not mention a recommended dose or duration. Parents in both studies were asked to record levels of their child's pain to determine effectiveness of pain control, but did not use a standard tool with known reliability and validity. Cook et al. (1992) recommended both aspirin and paracetamol as suitable analgesic choices, without any mention of appropriate dosing or duration.

Cook et al. (1992) reported a secondary haemorrhage rate of 15%, which was markedly higher than the Stollery Children's rate of 2-3% (C. Elliott, personal communication, November 1, 2002). Cook assumed that poor dietary intake was to blame for the elevated secondary haemorrhage rate, without giving consideration to the analgesic choice of aspirin. Thomas et al. (1995) examined child preferences for post-tonsillectomy diet, mentioning only that adequacy of hydration can be achieved by a number of considerations including "peri-operative analgesics." Finally Carabott et al. (1992) recommended that acetaminophen (10 mg/kg) be given every 4 hours until discharge, without mentioning the dosing and duration at home. Examination of pain control at home would be of interest in this population, as the children were not given the standard dose of acetaminophen (15 mg/kg) every 4 hours.

Recovery

Within the clinical and research literature "recovery" from tonsillectomy was not clearly defined. Brodsky et al. (1993) and Hall and Brodsky (1995) examined the effect of post-operative diet on recovery. Since they did not define "recovery" one is left to assume that "recovery" occurred when the child had adequate control over pain, nausea and emesis and tolerated the prescribed diet. The authors concluded that resumption of an early, regular diet based on parental discretion might be beneficial to recovery following a tonsillectomy. The Cook et al. (1992) study examined whether post-tonsillectomy dietary advice had any influence on recovery. Again, no operational definition was provided, and

recovery was inferred when the patient had adequate pain control, minimal analgesic requirements and "healing" tonsillar fossae.

Few authors mentioned any surgical variables and their influence on recovery. Brodsky et al. (1993) and Hall and Brodsky (1995) mentioned that surgeries were performed by one otolaryngologist, using cold knife dissection and cautery to minimize any study bias resulting from surgical technique. Cook et al. (1992) stated that the tonsillectomies were performed by dissection and either linen ties or cautery was used for haemostasis. Surgeries were performed by a team of surgeons ranging from senior to junior skill levels. Thomas et al. (1995) and Carabott et al. (1992) made no mention of surgeon or skill level.

The roles of dexamethasone and ondansetron on recovery post-tonsillectomy have been well studied. In a meta-analysis of dexamethasone use with tonsillectomy patients, Goldman, Govindaraj and Rosenfeld (2000) used a pooled analysis and found a 27% decrease in postoperative emesis attributable to the use of dexamethasone perioperatively. The use of dexamethasone also was found to increase the tolerance of both soft and regular diets at 24 hours post surgery by 22%. Similarly, Aouad, Siddik, Zaytoun and Baraka (2001) found that dexamethasone significantly decreased the incidence of emesis of 2-12 year old children in the 24 hours post-tonsillectomy, shortened time period to first oral intake and duration required for intravenous hydration. Litman, Wu and Catanzaro (1994) investigated the efficacy and safety of ondansetron in preventing emesis post surgery in 60 children undergoing tonsillectomy with or without adenoidectomy. The authors found that 77% of the children who received

ondansetron had no episodes of emesis 24 hours post-tonsillectomy. Morton, Camu, Dorman, Knudsen, Kvalsvik, Nellgard, Saint-Maurice, Wilhelm and Cohen (1997) also examined the efficacy and safety of ondansetron in 427 children, ages 1-12 years undergoing tonsillectomy, with or without adenoidectomy. The authors analysed emesis and nausea separately and found that significantly more ondansetron treated children had zero episodes of emesis and did not experience postoperative nausea and vomiting. Splinter and Rhine (1997) assessed the impact of high-dose versus low-dose ondansetron on vomiting following tonsillectomy. The authors concluded that the greater dose of Ondansetron (150 micrograms/kg) had a lower incidence (36% versus 52%) of postoperative vomiting ($p = 0.01$) when compared to low-dose ondansetron (50 micrograms/kg).

In summary, there was general consensus that early and continued fluid intake was critical to aid recovery. No significant differences were found with respect to fluids, soft diet, or rough diet on recovery, although authors did not provide a definition for the key variable of recovery. The assumption was made that restrictive diets could possibly lead to reduced oral intake, potentially increasing the incidence of secondary haemorrhage. Other potentially confounding variables included the differing surgical skill levels, dexamethasone and ondansetron use, humidity and the choice of analgesia offered post surgery. Only one study examined children's preferences, finding that children preferred liquids and soft diet. No study was found that examined the effect of dairy products on post-tonsillectomy recovery.

Assessing Pain Post Tonsillectomy

Due to the advent of same day surgery, parents are now managing their child's post-surgical course in the home setting. Therefore, postoperative pain management for tonsillectomy patients has become a major issue as parents take on the responsibility of assessing and intervening where healthcare professionals once did. Studies have consistently found that children's pain is underestimated by both medical staff as well as by parents, contributing to inadequate pain control (Chambers, Reid, Craig, McGrath, & Finley, 1998; Duff & Ziebarth, 1994; Rauen & Holman, 1989). Carter (1995) believed that the pain that children experienced after a surgical procedure could have direct psychological and physical consequences for the child, as well as an emotional effect on their immediate family. Perception of pediatric pain must always take into account the developmental stage that a particular child has reached, due to the fact that as children grow cognitively, their thoughts about the nature and experience of pain change (Hurley & Whelan, 1988). A number of factors related to pediatric pain have been studied and can be divided into the following categories: (1) developmentally appropriate assessment of pain; (2) issues related to pain measurement in children; (3) measurement tools; (4) parent-child agreement on pain intensity; and (5) pain control following tonsillectomy.

Developmentally Appropriate Assessment of Pain

Accurate assessment of children's pain requires consideration of the child's developmental level, the type of pain experienced, the history and context of pain, family influences and interaction with the health care team (McGrath,

1989). Hurley and Whelan (1988) examined children's responses of children to pain, based on their cognitive development according to Piaget. Preoperational children (ages 2-7) related to pain as a physical experience. When asked what is pain, children responded with "something that hurts." Concrete-operational children (ages 7-12) related to pain in the physical sense and were able to specify the location that pain was felt. When asked what is pain, children responded "a stomach ache, a headache." Whereas transitional-formal children (ages 10-12) were beginning to demonstrate awareness of connections, "if you keep ice on your ankle, you will have less swelling." When asked what pain is, the 10 to 12-year-old children responded " lots of kinds, moral pain, physical pain." Finally, children in the formal-operational group (ages 12 and older) were able to begin problem solving. When asked what pain is, children responded, "when you fall down you hit something, your nerves hurt." These findings illustrated the need for both healthcare professionals and parents who were caring for a child in pain to elicit and share information at appropriate cognitive and emotional levels.

The American Academy of Pediatrics (AAP) Task Force on Pain (2001) stated that acute pain was one of the most common adverse stimuli experienced by children, yet pain had been consistently under treated in the pediatric population. Acute pain resulted from injury, illness and necessary medical procedures. It was the responsibility of any healthcare professional caring for children to assist in eliminating pain and suffering when possible (AAP, 2001) and therefore a joint task force consisting of the AAP and the American Pain Society (APS) was established to address the assessment and management of

acute pain in infants, children and adolescents. Pain is a subjective experience that has sensory, emotional, cognitive and behavioural components (AAP and APS, 2001). Multiple barriers existed when treating children's pain. Some examples of these barriers included: the myth that children do not feel pain the way adults do, lack of assessment and reassessment for the presence of pain and fears of adverse effects from analgesia. The committee determined that ineffective pain management resulted from numerous myths, insufficient knowledge among caregivers and inadequate application of knowledge (AAP and APS, 2001) and concluded with recommendations for opportunities for pediatric care providers to improve in their pain management in their pediatric population. The suggested strategies included the need for pediatric providers to expand their knowledge regarding pediatric pain assessment and management by using (1) appropriate tools and techniques, (2) anticipating and intervening during painful experiences and (3) using a multimodal approach to pain management (AAP and APS, 2001).

The International Association for the Study of Pain (1979) defined pain as "a unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (p. 249)." In order to appropriately manage pediatric pain from infancy to adolescence, it was necessary to examine the literature for differences found due to cognitive and emotional development. Infants are preverbal and therefore are only able to communicate their pain through behavioural or physiologic responses. Infant behavioural cues included flailing, withdrawing limbs, rigidity in limbs, vocalizations, cry patterns and facial expressions, whereas physiologic responses

to pain reflected a more global response across all age ranges and included: an increase in heart rate, respirations, palmar sweat response and blood pressure (Frank, Greenberg, & Stevens, 2000; McGrath, 1989).

Toddlers and preschoolers may not understand the word 'pain' but were able to vocalize pain through their own vocabulary with words such as: "hurt," "owies," "boo-boo" or "ouch" (Frank et al., 2000). Davis (1990) studied nurses' misconceptions associated with the assessment and intervention of postoperative pain in toddlers. Common misconceptions included: 1) a sleeping child has no pain, (2) a child playing has no pain, (3) intramuscular method is the best route for pain medication and 4) children do not feel pain. Davis (1990) found that in contrast to previous studies the nurses did not hold these misconceptions about pain in toddlers. The nurses in the study were knowledgeable about postoperative pain assessment in toddlers, but were inconsistent in their chart documentation.

School-aged children and adolescents were able to communicate their pain in more abstract terms, providing detailed descriptions of their pain intensity and quality (Frank et al., 2000). Children in this age range may show less overt behaviours in response to pain, as children over the age of seven years were starting to recognize the psychological components of pain (Beyer & Wells, 1989; Frank et al., 2000).

Issues Related to Pain Measurement in Children

Many pain measurement tools are available for use within the pediatric population, but the extent to which they have been tested and demonstrate strong reliability and validity varies markedly. Appropriate tools need to be selected

according to the child's age; sex, cognitive level and type of pain experienced (McGrath, 1990) and included physiologic measures, self-report measures and behavioural measures. A brief description of some of the available tools for various age ranges will be discussed, with greater emphasis on two tools, the visual analogue scale and the faces scale.

Since infants are preverbal, facial expressions have been the more comprehensively studied indicator for this population and should be considered the gold standard (Frank et al., 2000). The facial expressions of infants experiencing acute pain were evaluated using the Neonatal Facial Coding System (Grunau, Johnston & Craig, 1990). This observational scale included assessment of the following facial features, for example an infant in pain would have: eyes forcefully closed, brows lowered and furrowed, nasal roots broadened and bulged, deepened nasolabial furrow, a square mouth and taut cupped tongue (Grunau et al., 1990). A multidimensional tool that included both behavioural and physiologic parameters is the CRIES with indicators of: crying, oxygen saturation, heart rate, blood pressure, expression and sleeplessness (Krechel & Bildner, 1995). A child as young as 3 years of age could localize their pain and a large volume of research has focused on developing reliable self-report measure for toddlers and preschoolers. The Poker Chip Tool has been used in children ages 4.5 to adolescence. Children were given four red poker chips and the child then chose from 0 "no hurt" to 4 "most hurt one could have" (Hester, 1979). An additional self-report scale for use with children over the age of 3 was the Oucher; it included 6 photos of children depicting facial expressions of "no hurt" to

"biggest hurt" with a numerical scale from 0-100 (Beyer & Wells, 1989; Frank et al., 2000). Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) is a behavioural pain scale developed for use in the post-operative period for ages 1-7. Six behaviours, crying, facial expression, verbal expression, torso expression were rated every 30 seconds by a trained observer (McGrath, 1989). Numerical values were then assigned based on the child's behaviour as positive (0), neutral or pain free (1), mild pain (2), moderate pain (3) or severe pain (4). Older adolescents may be able to use the McGill Pain Questionnaire, a multidimensional pain tool that included a total of 78 verbal descriptors of pain and a graphic rating scale (Melzack, 1983).

Abu-Saad (1984) assessed children's responses to pain using physiologic, behavioural, word descriptors and visual analogue scales (VAS). Her results suggested that children, whose pain experience was evident from the behavioural scale and the word descriptors, consistently selected high numbers on the VAS (Abu-Saad, 1984). The data showed that children age nine and above could reliably use the VAS and could describe their pain experience using word descriptors. Case studies showed that the pain experience of the child was not adequately communicated to health care professionals. Standing "as needed" orders for analgesia were not consistently given, leaving the children's pain under treated. Abu-Saad's study indicated that pain assessment tools are needed to aid health care providers in the assessment of children's pain.

Tesler, Holzemer and Savedra (1998) studied post-surgical responses of older children and adolescents 3 times every 2 hours for 12 hours on the first 3

postoperative days. The purpose of the study was to identify and record pain behaviours exhibited by children and adolescents during the first three postoperative days and to examine the relationship between behaviours and self-report of pain intensity (Tesler et al., 1998). Data was collected using the Word Graphic Rating Scale (WGRS), a visual analogue scale having a 100 mm line anchored by "no pain" and "worst possible pain" and the Pediatric Pain Behaviour List (PPBL), a tool that was designed for the study consisting of 47 behaviours. The authors found that the most frequently observed pain behaviours were "calm, maintaining one position, and flexing limbs" (p. 43), numerous children who were lying in one position, with calm expression, rated their pain as moderate to severe. This study showed the benefits of using both a behavioural and verbal pain scale for older children and adolescent's pain measurement.

Gillies, Smith and Parry-Jones (1999), in a 3-year study, investigated postoperative pain following elective surgery in the adolescent population. Data were collected using the Adolescent Pediatric Pain Tool (APPT), which consisted of a 10 cm word graphic rating scale, a coloured visual analogue scale, the Hospital Anxiety and Depression Scale (HADS), and the Offer Self-Image Questionnaire-Revised (OSIQ-R). Gillies et al.'s (1999) study demonstrated that adolescents' postoperative pain was under treated and influenced by both the presence of anxiety and depression, in addition to their developmental stage (Gillies et al., 1999). Lack of formal training in adolescent healthcare was reflected in the poor understanding of the needs of adolescents, with generalizations made such as "asking for pain relief was a means of attention-

seeking, adolescents clock-watch for drugs" (p. 213). By understanding the emotional and developmental needs of this distinct group, the pain management of adolescents would be improved.

Measurement Tools

After review of the literature, the faces scales for pain assessment were found to be the most applicable to this pilot study's population. The most frequently used faces scales available for use in the pediatric population were the Faces Pain Scale (FPS), Faces Pain Scale Revised (FPS-R) and the Wong-Baker Faces Scale.

Bieri, Reeve, Champion, Addicoat and Ziegler (1990) developed the initial version of their faces pain scale for the self-assessment of the severity of pain experienced by children. This team conducted a 5-phase study to test the scale's validity and the ratio scale properties of the faces pain scale. In the first phase, children in grades 1-3 were asked to draw five faces showing various degrees of pain. These features were incorporated into five sets of seven drawings each. Children in the second phase were part of a pilot test narrowing the five sets to one and then additional groups of children rank ordered the faces and made comparisons of all the possible pairs. The third phase tested the equality of the intervals between the faces, and the fourth phase tested the spontaneous use of the scale in memory. Finally, test-retest reliability was examined in the fifth phase (Bieri et al., 1990). The first three phases included children from grades 1-3, phase four included children in grade 3, while in the fifth phase only children in grade 1 were included. Overall, Bieri et al. (1990) found that the scale

incorporated conventions used by children, achieved strong agreement in the rank ordering of pain, indicated that the intervals were close to equal and were treated by children as a scale. The authors stated that the test-retest data with a rank correlation coefficient of 0.79 suggested that the scale might prove to be a reliable index over time.

Hunter, McDowell, Hennessy and Cassey (2000) evaluated the psychometric characteristics of the FPS with 135 health preschool and school-aged children in 3 groups of the following ages: 3.5-4.5 years, 4.5-5.5 years, and 5.5-6.5 years. The FPS was presented to the children in four phases. In the first phase all 7 face cards were laid out and the children were asked to place the faces in order of pain expression. Children in the second phase were shown all possible pairs of cards, one pair at a time, in random order and were asked which expressed more pain. In the third phase children were given blocks that represented differing degrees of pain and were asked to line up the blocks with the faces representing "no pain" to the "worst pain possible." In the final phase 15 additional children were used for the test-retest reliability check. Children were shown all seven face cards and asked to choose the level of pain reflective of each card for nine different painful experiences, not all of which each child had experienced. Retest was completed one week later with the same scenarios. The authors found that the scale was both easily administered and that the scale's aims and intentions were understood even by the youngest of the group (3.5 years of age). Additionally, the scale was found to be both sensitive and discriminating, however the authors felt due to errors and difficulties encountered during the

various phases of testing that the FPS did not qualify as an interval scale due to errors elicited in the first and second phases. The author's results supported the contention that developmental maturity affected a child's capacity to estimate pain. Hunter et al. (2000) concluded that they were unable to obtain the test-retest reliability of the FPS stated by the original authors. However, a large degree of variability was found for the responses in which children had to "imagine" the painful experiences. The authors stated that after analysis, the sample size was much smaller than estimated; therefore the issue of test-retest reliability needed to be re-examined with a larger sample.

Hicks, von Baeyer, Spafford, van Korlaar and Goodenough (2001) revised the FPS to develop a common metric measure in pediatric pain assessment. The team conducted three studies in order to revise and validate the existing FPS developed by Bieri et al. (1990). The first study consisted of the derivation of the Faces Pain Scale-Revised (FPS-R) from the FPS. Fifteen adults, all of whom had had extensive exposure to children, were chosen from a university population. Participants were tested individually using the SAFE scale (a continuous 101 frame computerized presentation of the FPS) developed by Champion and colleagues and were told a number between 0 and 5 endpoints and asked to adjust the facial expression accordingly. Strong positive correlations were found (r = 0.97). Four faces representing equal intervals between the scales were chosen, with the original first and last faces from the FPS included for a total of 6 faces. The second study validated the FPS-R with 76 children, ages 5-12 years, who were having their ears pierced. Using both the Visual Analogue Scale (VAS), a

200 mm scale consisting of a black line, with endpoints labelled 'no pain' and 'very much pain' and the FPS-R, children were asked to rate how much "hurt" they had experienced with ear piercing. Each scale was scored 0-5. A strong positive correlation ($r = 0.93$) was found between the pain intensity ratings using the two scales. The third study validated the FPS-R with a convenience sample of 90 children, ages 4-12 years, in a children's hospital. Children were asked to estimate their pain using the FPS-R, followed by either the VAS or the coloured analogue scale (CAS), a long tetragon varying from narrow, white 'no pain' to wide, red and 'most pain' selected on a pre-determined random schedule. Each scale was scored 0-10. The authors found that even among the youngest children (age 4 years) the FPS-R and analogue scales were used in a consistent and reliable manner ($r = 0.84$). Hicks et al. (2001) have developed a FPS-R, based on either the 0-5 or 0-10 scale system that has been validated for children between the ages of 4-12 years. This provides a faces scale that both has appeal to children and has validated psychometric properties.

McCaffrey (2002) compared the Wong-Baker FACES pain rating scale and the Faces Pain Scale-Revised. The Wong-Baker Faces Scale consisted of six faces with an assigned rating of 0-5. Zero equalling no pain and 5 equalling the most intense pain. Each face was labelled with a short description ranging from "no hurt" to hurts worst." A potential drawback was that the "no hurt" and "hurts little bit" faces were smiling and the "hurts worst" face was tearful. A child may think that they cannot choose the "hurts worst" unless they were crying. The Faces Pain Scale-Revised (FPS-R; Hicks et al., 2001) had six faces conveying

increasing levels of pain intensity and was numbered 0, 2, 4, 6, 8, and 10. A strong positive correlation has been found between the FPS-R and the numeric 0-10 scale used with adults. The advantage of this scale was that there were no smile or tears depicted on the faces. McCaffrey stated that used correctly, either of these tools could help measure a child's' pain intensity.

Parent-Child Agreement on Pain Intensity

Many researchers have investigated the differences between what children and parents perceive the children's pain experience to be. Chambers, Giesbrecht, Craig, Bennett and Huntsman (1999) compared pain ratings from faces scales in the measurement of pediatric pain (75 children, aged 5-12 years) with their parent's ratings. The following 5 faces scales were chosen for the study: FPS (Bieri et al., 1990), 5 hand drawn faces by LeBaron and Zeltzer (1984), Kuttner and LePage (1989) and Maunuksela, Olkkola and Korpela, (1987) and 6 hand drawn faces by Wong and Baker (1988). The study examined the potential for bias in children's self-reported ratings using; "smiling" rather than neutral "no pain faces" scales, levels of agreement between child and parent reports of pain, and preferences of scales by parents and children. Following venipuncture, child and parental ratings of pain were obtained using the five randomly presented faces scales. The authors found that children had significantly higher pain ratings when using scales that started with a "smiling" face in comparison to "neutral" no pain faces scales. Girls rated more pain than males, independent of scale type. No differences were detected between age groups. Chambers et al. (1999) found that parental ratings across the scales were highly correlated, and that they also had

higher pain ratings when using "smiling" faces as compared to "neutral" faces. Preferences of both child and parent for scale type were that of "happy, cartoon-like" images. Chambers et al. (1999) concluded that variations in the format of scales do influence the pain ratings of children and their parents.

Chambers et al. (1998) studied the agreement between child and parent reports of pain. The authors found that many parents failed to identify clinically significant pain in their children, therefore parental report should not be solely relied upon. To obtain the most reliable and valid assessment of pain, information from both the child and the parent should be considered (Chambers et al., 1998). Manne, Jacobsen and Redd (1992) examined the assessment of pediatric pain. They questioned whether child self-report, parent ratings and nurse ratings measured the same phenomenon. The authors found that nurses' ratings mainly reflected obvious behavioural distress, parents' ratings reflected their own anxiety and their assessment of how much pain their child was experiencing, and children's ratings were associated with maturational development. Three implications emerged from the study: 1) different conclusions may be reached regarding the effectiveness of an intervention depending on who the raters are, 2) parental ratings should not be considered a substitute for child self-report and 3) nurse ratings of acute pain may most closely approximate objective assessment of pain and distress behaviours (Manne et al., 1992).

Contrary to previously stated findings, Moinpour, Donaldson, Wallace, Hiraga and Joss (1990) and Morgan, Peden, Bhaskar, Vater and Choonara (2001) found that parent-child agreement was similar for pain measurement. Moinpour et

al. (1990) studied parent and child agreement in rating mouth pain of 22 children following radiation and chemotherapy using a visual analogue scale daily. They found that overall there was good agreement between parent and child reports of pain and are therefore entitled to the "same presumption of validity afforded adult reports of their own pain (p. 76)." Similarly, Morgan et al. (2001) studied the assessment of pain by parents in 50 young children following surgery using an observational scale used at the study hospital, which had not been formally validated. The authors found that parents could indeed assess postoperative pain in their young children. Through the use of a simple pain scale, with instructions to administer analgesia, parents were able to improve the pain management of their children following day-surgery.

Demyttenaere, Finley, Johnston and McGrath (2001) studied pain thresholds in children after major surgery using a self-report pain scale and agreement between parent-child and nurse's impression of the child's pain treatment thresholds. The authors defined "pain treatment threshold" as "amount of pain that is acceptable or tolerable before desiring analgesia" (Demyttenaere et al., 2001). The authors concluded that the pain treatment thresholds were lower in children after major surgery as compared with minor surgery. The investigators hypothesized that children experience more postoperative pain after major surgery compared to minor surgery and this sensitization is reflected in their pain intensity ratings (Demyttenaere et al., 2001). The study showed that parents and nurses were not accurate in rating the child's pain treatment thresholds and that parents tended to overestimate their child's pain treatment threshold.

Pain Control Following Tonsillectomy

As day surgery for tonsillectomy is now common practice, parents are increasingly becoming responsible for the management and assessment of their child's pain. This requires parents to become knowledgeable in the pain control of their child in the home setting. There were very few studies that examined the role of pain control in the tonsillectomy population. Rauen and Holman (1989) retrospectively examined pain control in hospitalized children following tonsillectomies. The authors found that children received adequate analgesia that provided adequate pain control "most of the time," 7 out of 50 children experienced ineffective pain control. Fewer analgesic doses were documented for the night and afternoon shifts when compared to the day shifts. Non-analgesic methods of pain control were consistently used in the study population.

The study by Duff and Ziebarth (1994) was the only one found that examined how mothers managed their child's post tonsillectomy pain at home. Using a qualitative approach, Duff and Ziebarth (1994) interviewed mothers about their experiences in assessing and managing their children's acute pain associated with adenoid-tonsillectomy surgery. Four themes emerged from the authors data: 1) mothers' descriptions of their children's overall pattern of postoperative pain indicated that there was minimal or absent pain prior to surgery, increased pain following surgery and decreased pain with medicine and healing; 2) mothers' assessment of their children's pain used pain cues were similar to those used by nurses and physicians; 3) all the mothers worried about drug addiction; and 4) mothers learned to manage their children's pain through

"trial and error." These findings reinforced the need to include family members early in the discussion both surrounding the surgery and possible interventions for the post-tonsillectomy period.

In summary, the literature demonstrated that as a result of multiple factors, pediatric pain has been under treated. Accurate assessment and management of pediatric pain is dependent on many factors, with cognitive and emotional development being only a few. It is essential that the child's age and developmental level be assessed prior to choosing a pain assessment tool. Families should be actively involved in decisions surrounding the assessment and management of their child following surgery, with realistic interventions offered by healthcare professionals.

Conclusions

Tonsillectomy is now considered a safe same day procedure for otherwise healthy children. With this transition to home based care; parents now are responsible for managing their child's early postoperative pain and recovery. Adequate fluid intake is a key determinant of successful recovery. There is however, considerable debate surrounding post-tonsillectomy diet; in particular, the effect of dairy products on the recovering post-tonsillectomy surgical site is unknown.

Pain is one of the most commonly used indicators of recovery post tonsillectomy. Despite knowledge of how best to measure children's pain, there is strong evidence that children's pain continues to be underestimated and thereby under treated. The greatest pain post-tonsillectomy tends to occur on the second

postoperative day when the child is at home (C. Elliott, personal communication, September 5, 2002; Duff & Ziebarth, 1994). To optimize children's recovery, parents need to know how best to assess and manage their child's pain once at home. Of the available pain measures appropriate for 3-12-year olds, the FPS-R (Hicks et al., 2001) had the most extensive testing and the best psychometric properties and was used in this pilot study.

Chapter 3

Research Methods

Design

A classic experimental design was used. Children were randomly assigned to either the experimental group (i.e., those children who did not consume dairy products for the first three days post-tonsillectomy) or to the control group (i.e., those children who were provided the standard hospital tonsillectomy diet). Envelopes were numbered 1-46. Using odd/even numbers on a random numbers table, the group designation was marked on pieces of paper and sealed in the sequentially numbered envelopes. There were 23 in the non-dairy group, and 23 in the standard tonsillectomy diet group.

Several surgical variables are known to affect recovery rates following tonsillectomy. In this study the following surgical variables were controlled: the same surgeon performed each tonsillectomy (no residents were involved) and each child received 1 pre-operative dose of acetaminophen, 1 intra-operative dose of dexamethasone with a subsequent dose 4 hours later and 1 intra-operative dose of ondansetron. Recovery was operationally defined as the meeting of the following four criteria: 1) pain ratings of zero, 2) no analgesia being consumed, 3) parental report that the child was able to play independently and return to day-care/school, and 4) the child was tolerating a soft diet, based on dietary assessment by a pediatric dietician. All four criteria must have been met for recovery to occur.

Setting

The study was conducted at The Stollery Children's Hospital, an acute pediatric treatment facility that serves as a referral centre for Alberta, Saskatchewan and Manitoba. Data were collected in the home setting after the child had undergone a tonsillectomy. Children in the study proceeded through Day Ward following tonsillectomy, were discharged to home 4-6 hours after, or were admitted to an observational inpatient pediatric unit.

Sample and Recruitment

The target population was otherwise healthy children ages 4-12 years, who underwent tonsillectomy/adenoidectomy or tonsillectomy surgery. Children were recruited from a pediatric otolaryngology office in Edmonton, Alberta at their preoperative office visit. On average, there are a total of 120 tonsillectomies performed annually by the otolaryngologist in the recruiting office. The average number of tonsillectomy surgeries performed per month is 10. For this study, a nonprobability sample of 45 children between the ages of 4 and 12 years and their primary caregivers were recruited. Considering that not all children met criteria, and not all parents were willing to consent, the time period for data collection was estimated to be 6 months to allow for a total recruitment of 45 children. Criteria for entrance into the study included:

1) Children who had recurrent tonsillitis; or
2) Children who had obstructive sleep apnea syndrome due to tonsillar/adenoid hypertrophy; and
3) Children who regularly consumed dairy products; and

4) Children between the ages of 4-12 years

Exclusion criteria for the study included children with:

1) Conditions associated with feeding and swallowing difficulties:
   a. Cleft lip and palate
   b. Down Syndrome
   c. Velocardiofacial syndrome
   d. Gross Developmental delay
2) Adolescents (not the typical age group for tonsillectomy); and
3) Non-English speaking families (researcher unilingual).

Power Analysis

To determine the power of this study design to detect statistically significant differences between groups, a power analysis was conducted (Cohen, 1988). No literature was uncovered to guide the selection of the effect size for this study. Lipsey (1990) describes the actuarial effect size approach to determining the effect size in the absence of literature. Typically clinically observable differences are thought to represent moderate to large effect sizes. Anecdotally, Dr. Elliott changed his postoperative practice due to his clinical observation of a treatment effect of withholding dairy products. Assuming a moderate to large effect size of 0.5-0.8, a power of 0.8, alpha of 0.05 for two tailed testing, suggested a sample size of 26 (ES = 0.5) to 64 (ES = 0.8). A sample size of 46 was appropriate for the pilot test and sufficient to determine ES and full sample for the full trial.

Definition of Terms

Many of the terms used to describe post-operative diets and post-operative recovery are also used in every day language. The following specific definitions were developed for this study.

Dairy and dairy substitutes. For the purpose of this study, the term dairy products included: milk, yoghurt, ice cream, pudding and cheese. Soy and soy by-products were also considered to be part of the dairy family for this study.

Soft diet. For the purpose of this study soft diet referred to foods that were soft and easily swallowed to minimize the risk of airway obstruction (scrambled eggs, pasta or porridge).

Rough Diet. For the purpose of this study rough foods were defined as foods that had crunchy consistencies such as pretzels, chips, popcorn, toast, tacos or burgers.

Immediate Tonsillectomy Recovery Period. The immediate tonsillectomy period was the first, second and third day following tonsillectomy surgery.

Recovery. Recovery was operationally defined as the meeting of the following four criteria: 1) no further complaints of pain based on the FPS-R, 2) no further analgesia consumed, 3) parental report that the child had reached a level of activity where he/she was able to play independently and/or go back to day-care or school, and 4) the child was tolerating a soft diet. All four criteria must be met for recovery to have occurred.

Measures

Demographic Data

Demographic data were collected using a form developed for this study. Data collected included the child's age, reason for tonsillectomy, date of surgery, weight of child, sex of child, ethnicity of child, day dairy started, day soft diet tolerated and whether or not a humidifier was in the home (Appendix A).

Food Tolerance

A data sheet was completed over ten days and included a list of foods eaten and fluids consumed (Appendix E). Once the data sheets were obtained from the family, a registered pediatric dietician reviewed the food intake log to determine the adequacy of nutrition. Once the child was consuming a soft diet that provided adequate nutrition, it was assumed that the child was tolerating the soft diet.

Analgesia

A data sheet was completed during the first 10 days post-tonsillectomy that included the number of doses of acetaminophen taken and time of doses (Appendix E).

Activity Level

With every acetaminophen dose and pain rating, parents were asked to record their child's level of activity. It was not expected that a child would return to their 'normal' level of activity for at least four weeks post-tonsillectomy. No rating of activity level sensitive to children's postoperative recovery was available in the literature. The following four point rating scale was developed for this

study. Parents were asked to assess their child using a four-level activity rating. In level one, the least active, the child was lying on the couch or bed doing nothing. In level two the child was sitting on the couch or bed, engaged in some quiet activity. In level three the child was playing independently. In level four the child had returned to day-care or school (Appendix E).

Pain Intensity

The child's reported, versus parent reported, pain intensity was measured using the FPS-Revised (Hicks et al., 2001) (Appendix C). This scale was developed for use with children aged 4-12 years. It has demonstrated concurrent validity with the linear visual analogue scale ($r = 0.93$) and a sliding scale measure ($r = 0.84$). Permission to use the FPS-Revised and example of the scale is included in Appendix B. Pain measurement occurred before every dose of acetaminophen. When the child was no longer consuming acetaminophen, pain measurement, along with activity level, occurred once a day, for a total of 10 days. Pain measurements continued for 10 days regardless of whether the child reported pain.

Complications

Postoperative complications such as nausea, vomiting, dehydration and bleeding were recorded by postoperative day and time (Appendix E). Bleeding was defined as at least one tablespoon of frank blood in the child's mouth. Nausea was defined as any report by the child of "feeling like throwing up" or any other report that the primary caregiver interprets as nausea. To distinguish vomiting from spitting mucous, vomiting included stomach contents. Reportable symptoms

of dehydration included the child having dark circles under their eyes, peeing less than usual for their child, and a dry mouth or tongue.

Procedures

Ethical Considerations and Consent

Participation in this pilot study was voluntary. The pediatric otolaryngology secretary approached parents(s) with introductory information about the study to see if they were interested in hearing more about the study. Parent(s) were told that the purpose of the study was to test whether withholding dairy products for the first three days postoperatively shortened the recovery period post-tonsillectomy. A copy of the information pamphlet was given to parents to read while the principal investigator was called to speak with the parents (Appendix C). This explained exactly what the extent of parents' involvement would be should they choose to take part in the study. If the parent(s) agreed to be involved in the study, the principal investigator obtained consent for participation in the study at that time (Appendix D). Confidentiality was maintained throughout the study. The primary investigator kept the child's name and identifying code number separate from the data and secured in a separate location. Ethical clearance to conduct the study was obtained from the University of Alberta, Health Research Ethic Board: Panel B and the CHA Regional Research Administration (Appendix G). A letter of support for recruiting from the referring otolaryngology practice and a letter of support for contacting parents in the Day Ward at the Stollery Children's Hospital is appended (Appendix H & Appendix I).

As patients were identified for tonsillectomy surgery, the office receptionist reviewed the child's chart to see if he or she met the inclusion criteria. After surgical consent had been signed, the secretary asked the parent if she or he was interested in finding out about the study. If parents indicated an interest, the principal investigator spoke to the parent and explained the study in detail.

Instructing Parents and Children

General post-tonsillectomy instructions were consistent for every child. The child was allowed clear fluids only for the first day, with a resumption of a soft diet on the second day (for a total of three weeks). The child was to stay at home 'pampered' for the first week. In the second week the child could return to day-care or school, as long as he/she was not requiring analgesia. Once in school the child was not allowed to participate in recess, sports, or gym for a total of two weeks. Swimming was not allowed for one month. Acetaminophen was the analgesia of choice and dosing was based on the child's weight. Ibuprofen and aspirin were contraindicated due to the associated potential for bleeding.

Each of the following measures was reviewed with parents. They were given a sample sheet that demonstrated what a complete data sheet might look like. As each of the measures was explained, parents were asked to provide examples or ask questions to ensure that they fully understood the instructions.

Pain assessment ratings. Once consent was obtained, the principal investigator explained the FPS-Revised to the child and the parent. The instructions were done according to the following standardized script: "Hurt" or

"pain" was used in the following instructions depending on the child's vocabulary. "These faces show how much something can hurt. This face (point to face farthest left) shows no pain. The faces show more and more pain (point to each from left to right) up to this one (point to face farthest right) it shows very much pain. Point to the face that shows how much you hurt right now." (Appendix B) The pain scale was reviewed again following surgery.

Analgesia. Acetaminophen was recommended, 15mg/kg every four hours for the first two days, then as needed by the child. The primary investigator approached parents in the recovery ward with dosing/time instructions, as well as with a demonstration on how to correctly document their child's' Acetaminophen consumption on the data sheet.

Dietary instructions. Prior to discharge, the principal investigator reviewed with the child and parent(s) the tonsillectomy diet consisting of clear fluids for the first day and then followed by a soft diet for three weeks. Children in the control group were offered the standard postoperative diet, with the exception of dairy products for the first three postoperative days. Children in the experimental group were offered the standard postoperative diet, including dairy products. A sample diet sheet was provided to each family based on the standard post-tonsillectomy hospital diet. Parents were told the total daily fluid requirement that their child required at home. These fluid requirements were based on the child's weight in kilograms (kg) following the Stollery Children's Hospital standard fluid calculation algorithm. The first 10-kg was multiplied by four, the second 10-kg was multiplied by two and the remaining kg's were

multiplied by one, then added up for a total ml/hour. This provided the family with the fluid intake volume for a 24-hour period. Families were advised to use a graduated container that enabled easy recording of total fluid amounts.

Activity Level. The four level activity scale was reviewed with parents. Parents were shown a sample data sheet. Their understanding of each of the four levels was confirmed through example.

Data Collection

After the tonsillectomy was performed, the principal investigator approached parents in the Day Ward with the data sheet that was to be completed during the ten postoperative days. The parents were given a package with the data sheets and pain assessment tools that they were to be completing at home. At this time, general post-tonsillectomy instructions, and the possible complications that can occur: nausea, vomiting, dehydration and secondary bleeding were discussed with the parent/child. Management of each complication was discussed with the parent. In the event of any secondary bleeding, parents were instructed to immediately return to the hospital for possible surgical intervention. The package included stamped, addressed envelope, which was to be mailed back to the principal investigator.

Progress Monitoring

The primary investigator telephoned the family every day, for the ten days. The primary purpose of the phone call was to ensure that the child was progressing satisfactorily and that the primary caregiver did not have unanswered questions. The secondary purpose was to enhance the integrity of data recorded

by the primary caregiver. The primary caregiver determined the length of the phone calls. Field notes were recorded for these phone calls to identify issues or patterns to be addressed in subsequent studies. If datasets had not been received by day 17, reminder phone calls were made.

Data Analysis

All data was entered in SPSS (version 11) statistical software for analysis. A two-person approach to data checking and verification was employed. Data were screened for missing data and data errors prior to analysis. Standard inferential statistics were calculated for the following demographic variables to test for group equivalence: sex of the child, ethnicity, reason for surgery, season of surgery and home humidification (chi-squared), and age and weight of the child (t-test). To answer the first hypothesis, was there a difference to the recovery period if dairy products were withheld, a *t*–test was performed to determine the differences between experimental and control groups for pain, number of Acetaminophen doses and activity level. Then a chi-square test was used to make between group comparisons of the length of time taken to tolerate a soft diet. The pilot study utilized an alpha of 0.05 and two-tailed testing for significant differences. To answer the second hypothesis, was there a difference in the number of incidences of post-operative complications if dairy products were withheld, chi-square analysis was used to compare the incidence of nausea, vomiting, dehydration and bleeding in the experimental and control groups.

Chapter 4

Findings

Sample

Forty-five children were identified who fulfilled the inclusion criteria and were enrolled in the study between the dates of March 10, 2003 and February 24, 2004. One parent refused participation in the study. Nine children were excluded from analyses: three data sets were lost in the mail, three were not returned, one had insufficient data, one surgery was cancelled and one child was withdrawn from the study. Seven of the nine children lost from the study were assigned to the control condition (i.e., non-dairy). For both of the children in the experimental condition (i.e., dairy group), the data sets were lost in the mail. A chi-square test indicated that there was not a statistically significant difference between groups in terms of number of children lost from study χ^2 (1) = 3.76, p = .071 (two-tailed). After exclusion of these nine children, the final sample size was 36. Of the 36 children, 15 were assigned to the non-dairy group and 21 to the dairy group.

Returned Data

There were approximately 120 tonsillectomy surgeries performed during the 1-year enrollment period. Due to strict recruitment criteria, in particular restrictions on age, only 46 (38%) children were eligible for study inclusion. One family that was approached regarding the study declined involvement, for a total of 45 children recruited. Thirty-seven data sets were returned, one with incomplete data, for a total of 36 completed sets. Therefore the overall return rate for the study was 82%.

Two families failed to return data sets at completion of the 10-day period. Each of these families were phoned on two separate occasions with a courteous reminder to mail back the data sets, as well as to ensure that they still had the stamped and addressed envelopes. Despite these attempts, data sets were never received. A further three data sets were lost in the mail. Each of these families were phoned one week following completion of the study to ensure mailing of data had occurred. All families were very upset that the data sets were never received, one mom stating, "Oh that was so much work, I can't believe you never got it." After these experiences, reminder phone calls were made to every family who lived outside of the Edmonton area on day 12 rather than day 17. When families lived in the Edmonton vicinity, data sets were personally picked up from families' homes. This resulted in a subsequent return rate of 100%.

One family was experiencing extraordinary number of competing demands. After completion of the study, phone calls were no longer returned, resulting in the sixth lost data set. One family opted to withdraw from the study on day 2, with the misconception that if her child was no longer in the study that the daily required amount of fluid intake would not have to be consumed. Despite a thorough explanation of the need for fluid regardless of study enrollment, the child was withdrawn from the study.

Demographics

The children's ages ranged from four to 12 years of age. The mean age of the sample was 7.64 years ($SD = 2.67$). Children in the non-dairy ($M = 7.87$; $SD = 3.00$) and dairy ($M = 7.48$; $SD = 2.48$) groups did not differ significantly in

terms of age, $t(34) = .48$, $p = .672$ (two-tailed). The children's weight in kilograms (kg) ranged from 15.3 kg to 63.3 kg ($M = 29.24$; SD 11.56). Children were primarily Caucasian (88.9%); followed by Asian (2.8%), Native Canadian (2.8%), African Canadian (2.8%), and mixed Caucasian and Native Canadian (2.8%). The sample was split evenly in terms of gender and no statistically significant difference in gender composition as a function of dairy or non-dairy group assignment was observed, $\chi^2 (1) = .114$, $p = 1.00$ (two-tailed).

All children in the study underwent the surgical procedure of a tonsillectomy and adenoidectomy. The reasons for surgery included obstructive sleep apnea syndrome (OSAS) (36%), recurrent tonsillitis (39%) and combined OSAS and recurrent tonsillitis (25%). Most (81%) of the children had a humidifier in the home. No statistically significant difference between groups was found, $\chi^2 (1) = .434$, $p = .367$ (two-tailed) in regards to home humidification. Surgeries were carried out over the four seasons, with equal group distribution. The greatest percentages of surgeries were carried out in the fall (33% for both groups) and spring dairy (29%), non-dairy (33%). Chi-square analyses indicated that there were no significant differences between children in each condition with regard to whether the surgery occurred in any particular season. Table 1 includes demographic information based on group selection.

Table 1

Demographic Information for Dairy and Non-dairy Groups

Demographic	Dairy Group		Non-Dairy Group	
	M	*SD*	*M*	*SD*
Age	7.48	2.48	7.87	3.00
Weight	27.75	1.04	31.32	12.33
	n	%	*n*	%
Gender				
Female	10	48%	8	53%
Male	11	52 %	7	47%
Reason for Surgery				
Obstructive Sleep Apnea Syndrome	11	52%	2	13%
Recurrent Tonsillitis	8	38%	6	40%
OSAS/Recurrent Tonsillitis	2	10%	7	47%
Humidifier in Home				
Yes	16	76%	13	87%
Season				
Winter	5	24%	4	27%
Spring	6	29%	5	33%
Summer	3	14%	2	13%
Fall	7	33%	4	27%

Research Hypothesis One

Recovery. It was hypothesized that children in the non-dairy group would recover earlier than children in the dairy group. Recovery was operationally defined as the meeting of the following four criteria: 1) no further complaints of pain based on the FPS-R, 2) no further analgesia consumed, 3) parental report that the child had reached a level of activity where she/he was able to play independently and/or go back to day-care or school, and 4) the child was tolerating a soft diet. All four criteria must be met for recovery to have occurred.

Only nine (25%) children in the total sample met criteria for recovery. However, an emerging trend became evident, with children in the non-dairy group recovering more quickly than children in the dairy group. Three (8%) children in the dairy group recovered by day 10, whereas 6 (17%) children in the non-dairy group had met criteria for recovery by day 10. No statistically significant difference was found between dairy and non-dairy groups in terms of recovery χ^2 (1) = 3.07, p = .122 (two-tailed).

Children in the non-dairy group tolerated a soft diet more quickly and were pain free and acetaminophen free earlier than children in the dairy group. Return to independent play was comparable for both groups, with children in the dairy group achieving independent play slightly earlier (days 6-8) when compared to children in the non-dairy group (days 7-10).

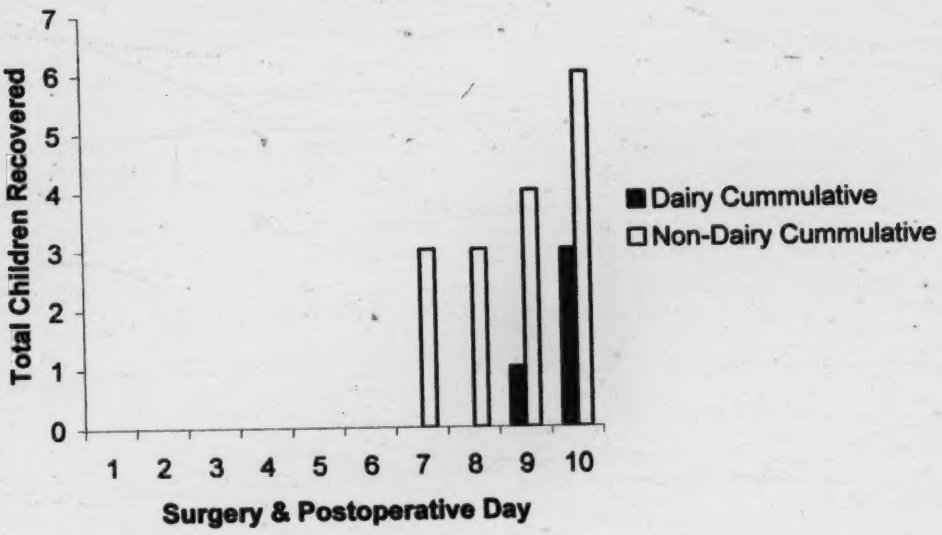

Figure 1. Recovery.

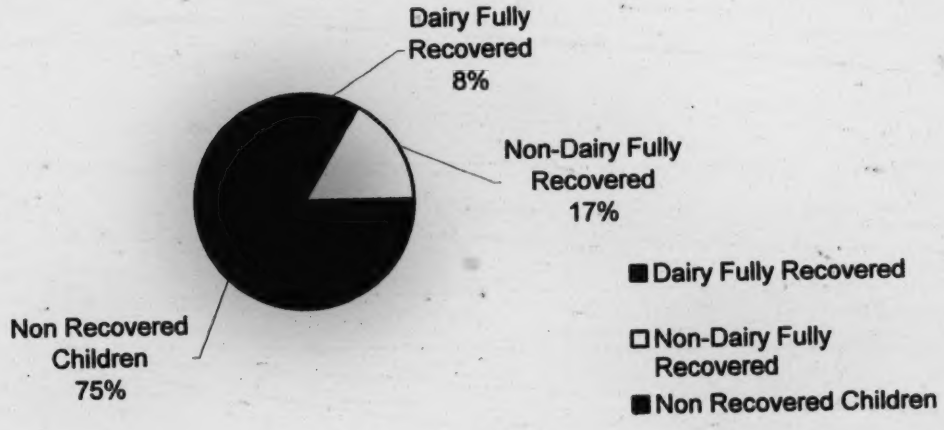

Figure 2. Total Sample Recovery By Day 10.

Acetaminophen Usage. It was hypothesized that children in the non-dairy group would consume less acetaminophen than children in the dairy group. Acetaminophen usage was comparable for the duration of the 10 days in both the dairy and non-dairy groups. Mean acetaminophen doses per day ranged from 1.3 to 5 for the dairy group and 1.3 to 4.3 in the non-dairy group. Acetaminophen usage was highest on day 2 (5 doses) in the dairy group and day 3 (4.3) in the non-dairy group, followed by decreasing dosing in both groups. No significant differences were found between groups with respect to acetaminophen dosing [(M_{Dairy} = 3.07, SD_{Dairy}= 1.16, $M_{Non\text{-}Dairy}$=2.77, $SD_{Non\text{-}Dairy}$ =1.31, t (34) = .736, p = .467 (two-tailed)].

Thirteen (62%) children in the dairy group and seven (47%) children in the non-dairy group were still requiring doses of acetaminophen on day 10 of the study period. Of these children, three (14%) in the dairy group and four (27%) in the non-dairy group required three or more doses on day 10. Eight (38%) of the children in the dairy group requiring acetaminophen at day 10 had complaints of ear pain versus 2 (13%) of the children in the non-dairy group. At the completion of the 10 study days, eight (38%) children in the dairy group and eight (53%) children in the non-dairy group did not require further doses of acetaminophen.

Interestingly, the two children in the dairy group and one child in the non-dairy group that required the most amount of acetaminophen for the duration of the 10-day study period, had pain intensity scores of "none" (ID # 35) and "low to none" (ID # 9, ID # 46) respectively. It is not known whether this pattern

reflects exceptional management of pain or routine dosing of acetaminophen despite low or no pain intensity scores.

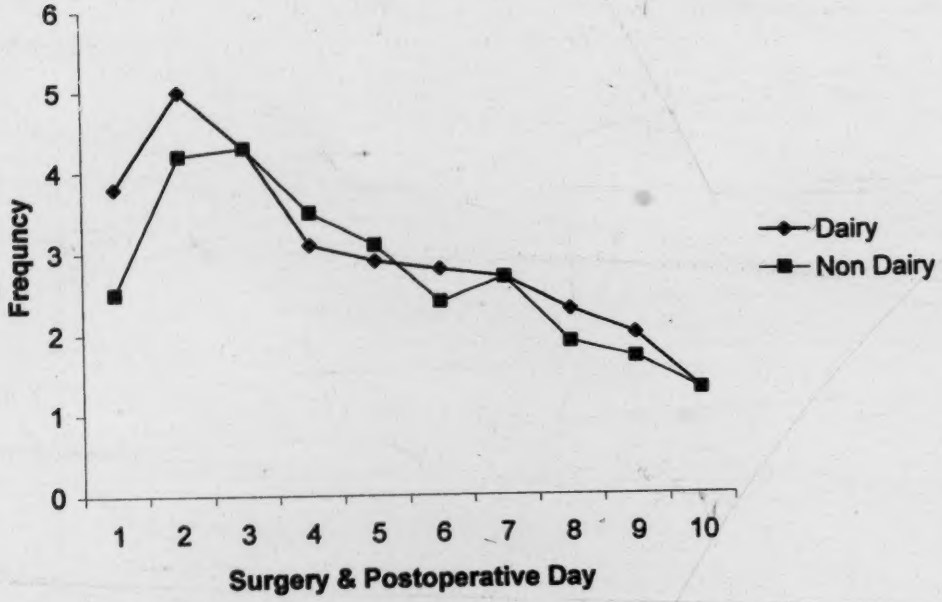

Figure 3. *Acetaminophen Usage.*

Pain Intensity. It was hypothesized that children in the non-dairy group would experience less pain over the 10-day study period when compared to the dairy group. Findings based on independent *t*-tests were contrary to this hypothesis. The difference in pain ratings reported by children in each group were statistically significant for days 1 and 3 of the study period, with pain ratings in the non-dairy group being higher for both days [Day 1: $t(27) = 2.30$, $p = .030$ (two-tailed) and Day 3: $t(33) = 2.15$, $p = .039$ (two-tailed)]. One might have then

expected the non-dairy group to consume more acetaminophen, but this was not the case. Both groups had similar dose requirements with the greatest need being on the 2nd and 3rd post-operative days.

For the entire sample, the average pain rating for the 10-day study period was 1.7 out of a possible pain rating of 10. The mean daily pain ratings ranged from 3.1 to 1.7 in the dairy group and from 4.4 to 1.8 in the non-dairy group. Pain ratings were highest on the surgical day for both groups (dairy = 3.1, and non-dairy = 4.4) then decreased incrementally over the 10 days. The dairy group had an increase in pain levels on day 5 and 7, whereas the non-dairy group had an increase on day 8.

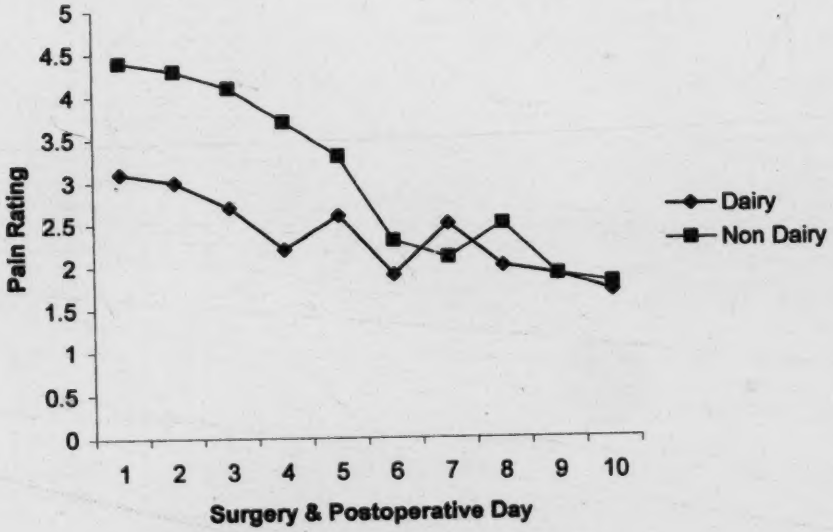

Figure 4. *Group Pain Ratings.*

For the purpose of statistical analysis, pain was operationalized as the following: no pain= 0, low pain = 1.0 to 3.9, moderate pain = 4.0 to 7.9 and high

pain = 8.0 to 10.0. Six (40%) children in the non-dairy group experienced moderate pain intensities, whereas only two (9%) children in the dairy group consistently experienced moderate to high pain intensities over the 10-day period. There was greater pain intensity variability among the non-dairy group.

Six of the eight children (six non-dairy and 2 dairy) who had consistent complaints of moderate pain intensities throughout the study period had compounding factors of decreased fluid intake affecting their recovery. Two of those children, one from each group, required hospitalization for dehydration. This further highlights the importance of adequate fluid intake to minimize pain and maximize recovery. One child sought medical attention for croup and one child had erratic pain ratings without documented complications.

Sixty percent of the children in the non-dairy group and 43% of children in the dairy group had no pain at the end of the study period. Six children in the non-dairy group (40%) and 12 children in the dairy group (57%) experienced pain throughout the study period. In the non-dairy group two children (13%) had 'low' pain scores, three (20%) had 'moderate' pain scores and one (7%) had a 'high' pain score upon completion of the study period. In the dairy group eight children (38%) had 'low' pain scores, three (14%) had 'moderate' and one (5%) had a 'high' pain score upon completion of the study

period.

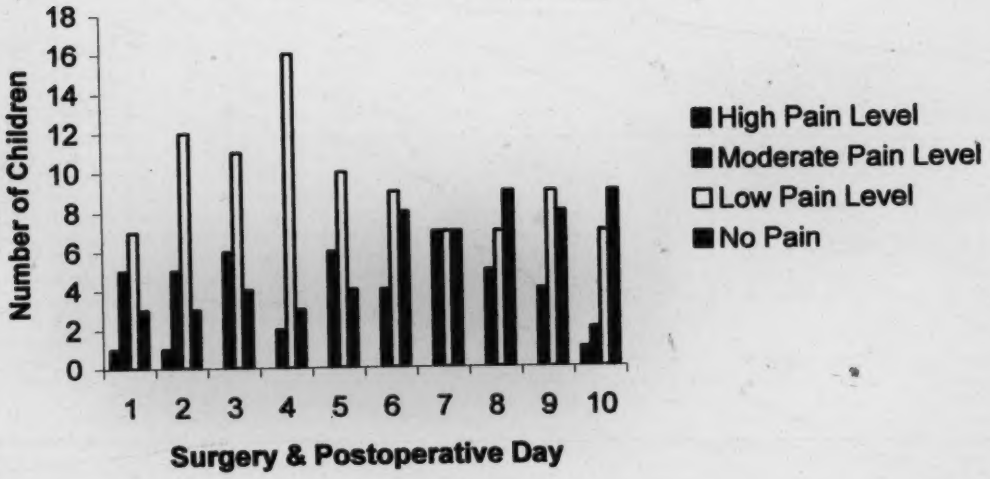

Figure 5. *Dairy Group Pain Ratings.*

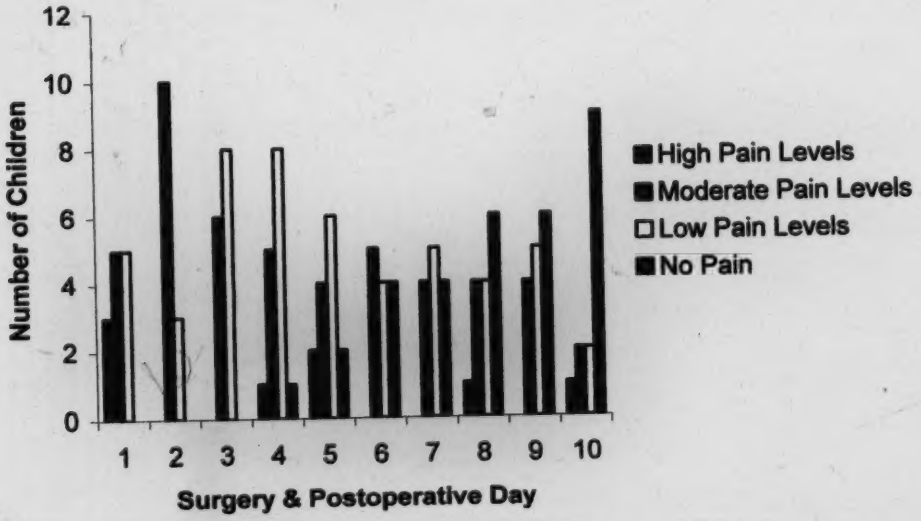

Figure 6. *Non-dairy Group Pain Ratings.*

Food Tolerance. It was hypothesized that children who did not consume dairy products in the immediate post-operative period would tolerate a soft diet more quickly than those children allowed to consume dairy products.

Although not statistically significant [dairy group ($M = 3.13$, $SD = .35$) and non-dairy group ($M = 2.86$, $SD = 1.42$)], a trend emerged from that data contrary to this hypothesis. Fifty-seven percent ($n = 12$) of children in the dairy group were tolerating a soft diet on day 2 versus 47% ($n = 7$) of children in the non-dairy group. This trend continued until day 5 of the study, when a greater number of non-dairy children were tolerating a soft diet. By day 7, all children were tolerating a soft diet. The child (ID # 37) who took the most amount of time to tolerate a soft diet was assigned to the dairy group and was admitted for decreased fluid intake on day 5 of the study.

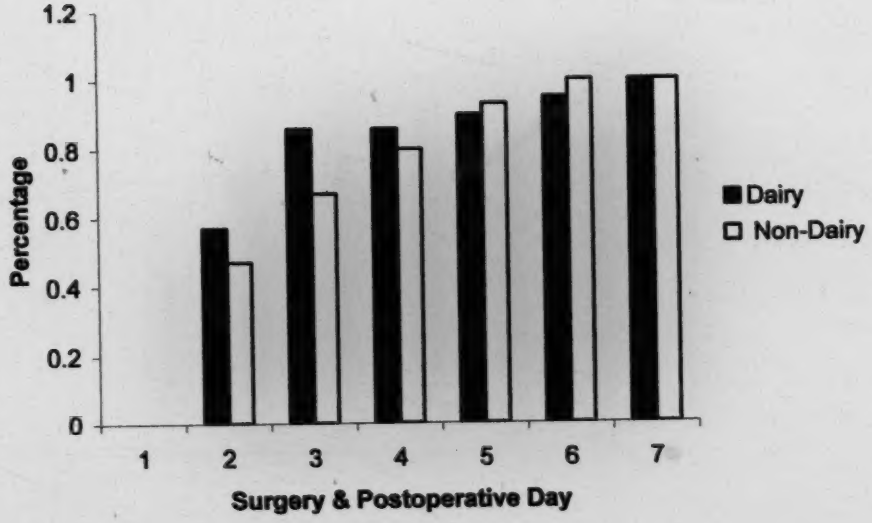

Figure 7. *Toleration of Soft Diet.*

Activity Levels. It was hypothesized that children in the non-dairy group would return to a normal level of activity earlier than children in the dairy group. Contrary to the hypothesis, activity levels for both groups were similar during the first six days of the study period. A divergence occurred on day 7, with an increased level of activity among the non-dairy group. The average activity level for the sample was 2.2 out of a possible score of 4. Average activity levels for the dairy group ranged from 1.3-2.5 and from 1.5-2.7 in the non-dairy group. In both groups average activity levels were lowest on day 1 (dairy group = 1.3, non-dairy =1.5) and highest on day 10 (dairy group = 2.5, non-dairy = 2.7). The non-dairy group increased steadily over the 10 days, whereas in the dairy group this trend was interrupted by a decrease in activity level on day 7. In fact, day 7 was the only day on which the differences between the groups was statistically significant per independent t-tests, with children in the non-dairy being significantly more active ($M = 2.56$, $SD = .73$) than children in the dairy group ($M = 2.05$, $SD = .69$), $t(33) = 2.07$, $p = .047$ (two-tailed). Ten (48%) children in the dairy group and eight (53%) children in the non-dairy group were back to independent play and/or back to day-care or school by the end of the 10 study days.

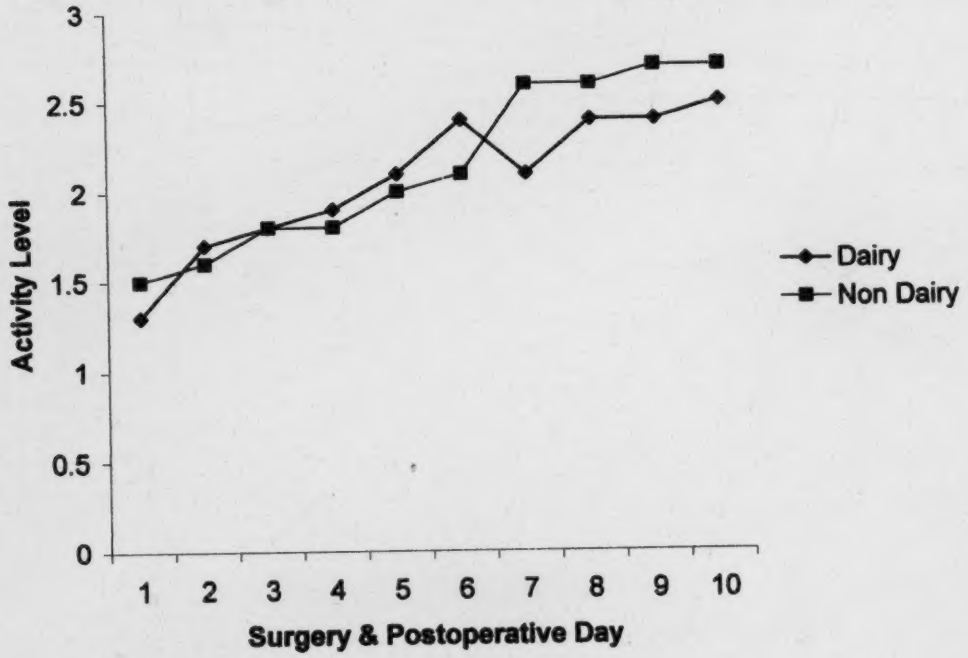

Figure 8. *Activity Level.*

Day Dairy Started. Considering the entire sample, 19 children started dairy products on day 2 (53%), 10 started on day 4 (28%), three started on day 5 (8%), two started on day 3 (5%), and one child started on day 8 (3%). One parent in the non-dairy group chose to withhold dairy for the 10 days. For children assigned to the dairy condition, 19 started dairy on day 2 (90%) and the remaining two children started on day 3 (10%). For children assigned to the non-dairy group, 10-started dairy on day 4 (67 %), three started on day 5 (20%) and one started on day 8 (7%). On average, children in the non-dairy condition (M= 4.25 days, SD = 1.76), received dairy approximately two days after the children in the dairy

condition did (M = 2.10 days, SD = .30), which supports the integrity of study design.

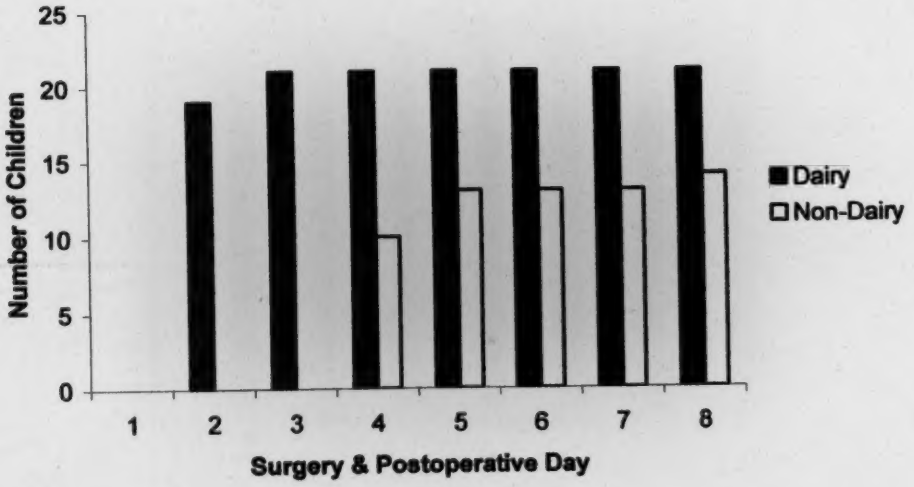

Figure 9. *Day Dairy Started.*

Research Hypothesis Two

Complications. It was hypothesized that children in the non-dairy group would have fewer incidences of nausea, vomiting, dehydration and bleeding. Contrary to this hypothesis, no significant differences were found between groups χ^2 (7) = 9.60, p = .212 (two-tailed). One child in the dairy group was admitted on day 10 for control of bleeding. There was no occurrence of post-operative bleeding in the non-dairy group. Both groups' experienced comparable incidences of nausea during the 10-day study period, a total of 34 recorded incidences for the dairy group versus 31 recorded for the non-dairy group. Children in the dairy group had greater recorded incidences of vomiting (28) as compared to the non-

dairy group (13) over the 10-day study period. To ensure completeness of data, statistical analysis was carried based on the presence or absence of a complication, versus the incidence of a complication. It is therefore uncertain if a significant difference would have been detected for the complication of vomiting, if analyses had been run for incidences. Two children in the dairy group were admitted for decreased fluid intake on day 2 and day 5. One child in the non-dairy group was admitted for decreased fluid intake on day 5. Both groups were without further complications by day 8. Thirty-eight percent of the children in the dairy group did not have any complications, whereas 33% of children in the non-dairy group did not have any. There were two children in each group who experienced increased episodes of nausea and vomiting. Of these children, one from each group was admitted for decreased fluid intake.

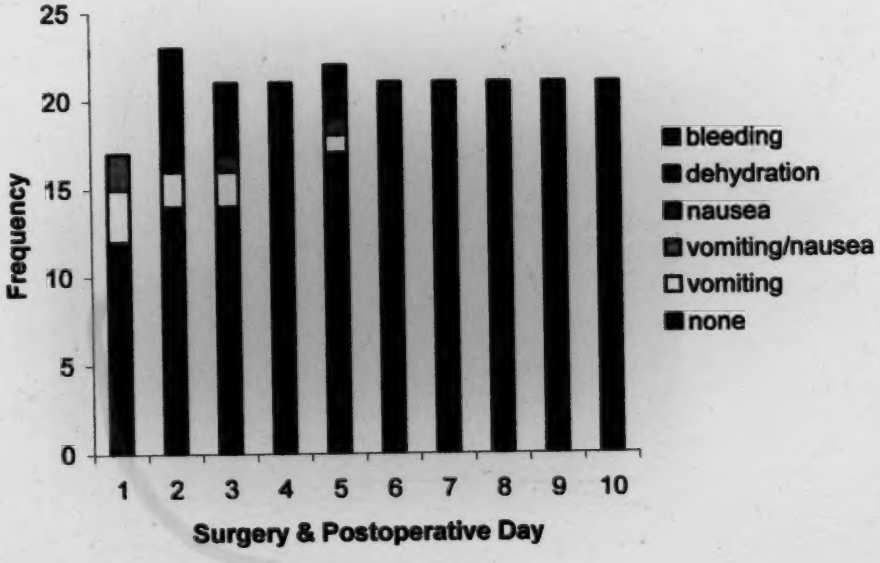

Figure 10. *Dairy Group Complications.*

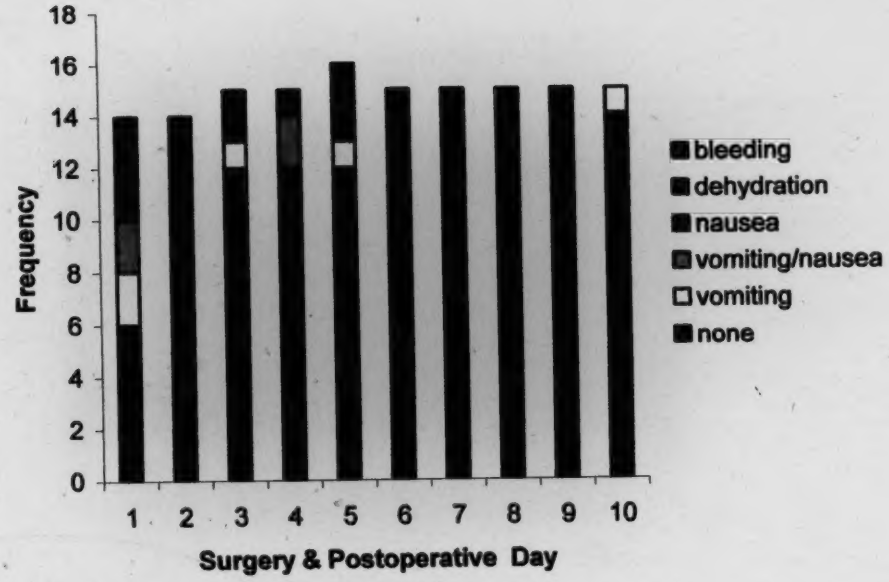

Figure 11. *Non-Dairy Group Complications.*

Secondary Morbidity. Common findings post-tonsillectomy in this study were: nausea (89%), vomiting (58%), otalgia (45%), voice changes (25%), halitosis (17%), neck pain (14%), jaw pain (8%), nightmares/sleep disturbances (11%), dehydration requiring hospital admission (8%) and secondary bleeding (3%). Complications occurred equally between the groups with the exception of otalgia. Thirteen (62%) children in the dairy group had complaints of otalgia as compared to only three (20%) children in the non-dairy group. This represented a significant difference between groups χ^2 (1) =4.97, p = .041. Onset of otalgia was evenly distributed between days 2-8. Fifty-two percent of children in the dairy group had a tonsillectomy due to OSAS. The significant finding of otalgia could possibly be related to adenoid hypertrophy associated with OSAS. For future

study there would need to be a systematic data collection for both otalgia and throat pain with associated pre-operative diagnosis. Only in the event of the presence of otalgia would the pain be rated using a VAS.

In summary, withholding dairy products in the immediate post-tonsillectomy period did not significantly shorten time to recovery in this sample. Although twice as many children in the non-dairy group (17%) recovered than the dairy group (8%), the sample size was likely too small to detect a significant difference. Withholding dairy products in the immediate post-tonsillectomy period did not significantly decrease the incidence of the following complications: nausea, vomiting, dehydration and secondary bleeding.

Chapter 5

Discussion

The purpose of this pilot study was to explore the practicality of a randomized controlled clinical trial to test the effect of withholding dairy products on post-tonsillectomy recovery. Recovery was defined as: the absence of pain, no requirement for analgesia, toleration of soft diet and return to independent play. Two hypotheses were tested; 1) there will be no difference in recovery time if dairy products are withheld in the immediate post-tonsillectomy period and 2) there will be no difference in the incidence of the following complications: nausea, vomiting, dehydration and secondary bleeding if dairy products are withheld in the immediate post-tonsillectomy period.

After statistical analysis, only 9 of 36 children met the criteria for recovery by day 10. Although no significant differences were detected, trends were evident, with twice as many children in the non-dairy group meeting the established criteria for a full recovery when compared to the dairy group. While no significant differences were detected, the strength of the study is found in the control of extraneous variables, pre-operatively, intra-operatively and post-operatively. This study is unique in its control of potentially confounding variables and suggests important design considerations for future studies. A schematic illustration of the variables and outcomes associated with recovery post-tonsillectomy is presented in figure 12.

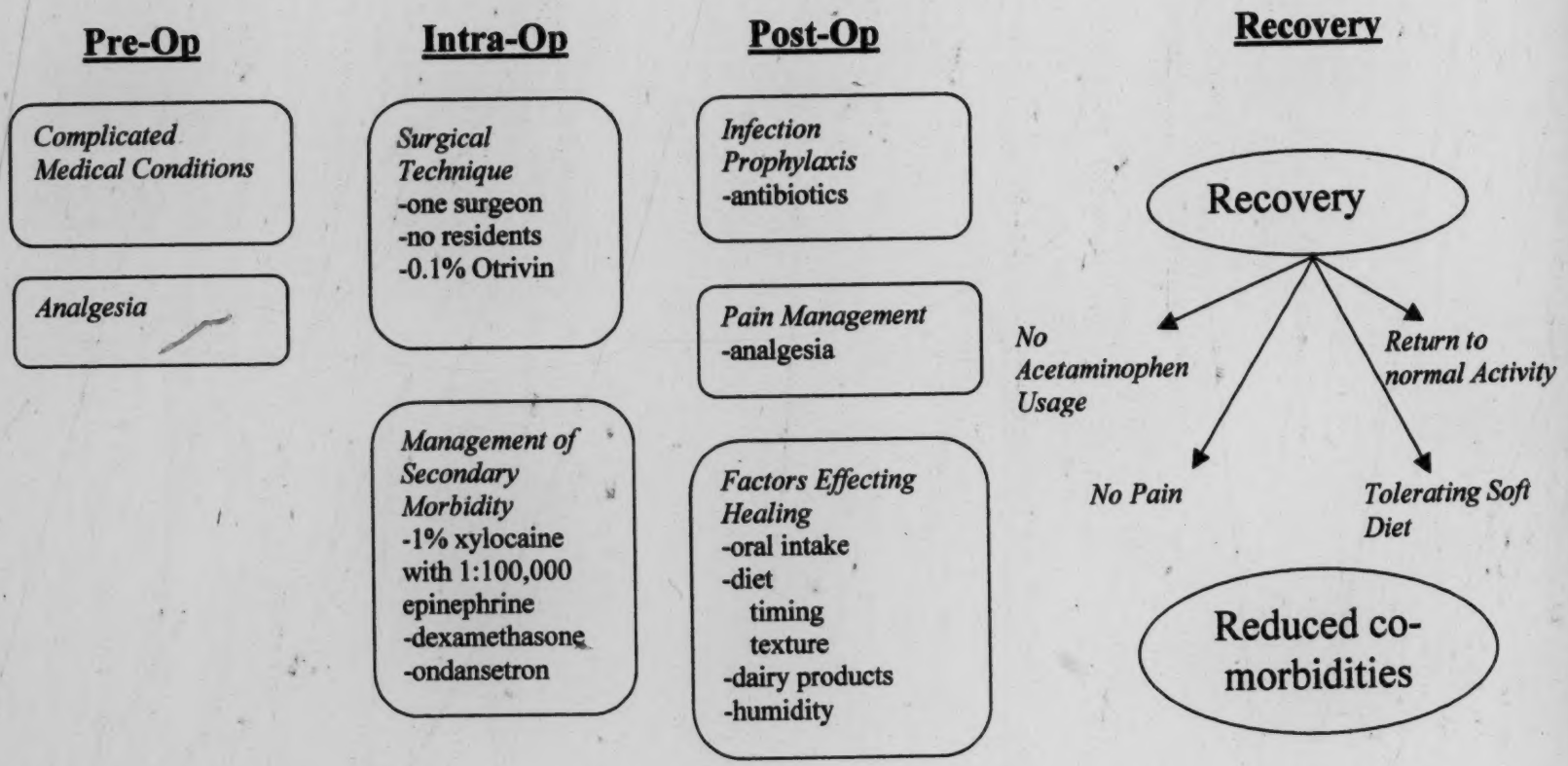

Figure 12. *Variables Associated with Post-Tonsillectomy Recovery.*

Pre-operative

Pre-operative Health Status. The referring otolaryngologists' practice was comprised of medically complex patients. To correct for potential skew in the clinical complexity and surgical risk of the sample population, strict inclusion and exclusion criteria were set to only include otherwise healthy children. Children with conditions associated with feeding and swallowing difficulties were excluded from the study, as diet and adequate fluid intake were key factors in the recovery process. Only two other studies specified the status of patients undergoing tonsillectomy as either being healthy children (Hamers et al., 2002) or children who did not have chronic illnesses or developmental handicaps (Finley, McGrath, Forward, McNeill & Fitzgerald, 1996). The 36 children were all seen by the referring otolaryngology practice for treatment of obstructive sleep apnea syndrome, recurrent tonsillitis or a combination of the two. No other study reported the reason for surgery.

Analgesia. Every child received one dose of acetaminophen (20 mg/kg) pre-operatively. Only one other study made mention to pre-operative analgesia and/or anxiolytics. Hamers et al. (2002) stated that midazolam was given to children 20-25 minutes prior to induction for tonsillectomy. No literature was found regarding pre-operative acetaminophen in the tonsillectomy population.

Intra-operative

Surgical Technique. It is reasonable to assume that there will be variation in surgical technique and skill between otolaryngologists. To control for this

variability, only one pediatric otolaryngologist (no residents) performed the tonsillectomies in this study. Two studies in the literature made mention to one pediatric otolaryngologist performing the tonsillectomies (Brodsky et al. 1993, Hall et al., 1995), whereas other studies used multiple general surgeons or adult otolaryngologists (Cook et al., 1992; Warnock et al., 1998; S. Wiggins, personal communication, May 19, 2004). As an example of variation in technique, the otolaryngologist in this study places 0.1% Otrivin soaked in cotton balls in either nostril at the beginning of each surgical case. The reason is twofold: for constriction of vessels and secondly to decrease inflammation. No other study mentioned this technique.

Management of Secondary Morbidity. Intra-operative medications are available to reduce some of the associated morbidities post-tonsillectomy, such as pain, emesis and nausea. The agent that has traditionally been used for local anaesthesia in tonsillectomies is 0.25% bupivacaine with 1:200,000 epinephrine (Ohlms, 2001; Jebels, Reilly, Gutierrez, Bradley & Kissin, 1993; Jebels, Reilly, Gutierrez, Bradley & Kissin, 1991). The pediatric otolaryngologist in this study used 1% xylocaine with 1: 100,000 epinephrine (4-5 ml) for local anaesthesia. Benefits of a local anaesthetic injection in tonsillectomies include the reduction of pain, diminished peri-operative bleeding and ease of dissection (Goldsher, Podoshin, Fradis, Malatskey, Gerstel, Vaida & Gaitini, 1996). One study of pain progression following tonsillectomy made an unexpected observation that differs from other studies. Warnock et al. (1998) found that children who had bupivacaine infiltrated into the tonsil fossa had significantly more pain ($p = 0.04$)

on the surgical evening when compared to children who did not receive bupivacaine.

Intra-operative use of dexamethasone serves a threefold purpose. It is has proven efficacy in reducing post-operative emesis, pain, as well as in shortened time to oral intake and advancement to soft diet (Goldman et al., 2000; Aouad et al., 2001; Steward, Welge, & Myer, 2003; Elhakim, Ali, Rashed, Riad, & Refat, 2003). In this study all children received one intra-operative dose of dexamethasone (0.1 mg/kg) as well as one dose 4-hours post-operatively. Intra-operative ondansetron has proven to reduce nausea and vomiting post-tonsillectomy (Litman et al., 1994, Morton et al., 1997). In this study every child received one intra-operative dose of ondansetron.

Post-operative

Infection Prophylaxis. Antibiotics are used as adjunct therapy post-tonsillectomy to decrease possible pharyngeal inflammation from bacterial colonization (Thomsen & Gower, 2002). Specific benefits of antibiotic therapy may include pain reduction, improved oral intake and decreased post-operative bleeding (Thomsen et al., 2002; Telian, Handler, Fleisher, Baranak, Wetmore & Potsic, 1986). All children in this study were prescribed an oral antibiotic post-tonsillectomy to be taken for the 10-day duration. No other study in the tonsillectomy literature reported antibiotic prescription.

Pain Management. Parents were instructed to give acetaminophen around the clock, every four hours, on the surgical day and the day and night following surgery. The importance of wakening a child for his or her nighttime dose of

acetaminophen during the first two days was strongly emphasized to parents. As well, the importance of fluid intake was stressed in conjunction with acetaminophen dosing during the night, "when you wake Billy for his acetaminophen have him drink some water." It was re-enforced that children who did not receive analgesia and fluid during the night had a more painful waking and more difficult start to the day.

Of note, only one child with attention deficit disorder required a prescription for codeine on 2nd post-operative day with complaints of low to no pain with poor oral intake. A total of 6 doses were given over four days.

Factors Affecting Healing. Four factors that could potentially affect healing of the surgical site are: fluid intake, texture and timing of diet, humidity and dairy products. To maintain hydration of the surgical site, the importance of oral intake was emphasized to parents. Every child was required to consume a calculated amount of oral fluids daily based on his or her weight. The importance of nighttime sips was stressed as it aided in hydration of the throat and in achieving the daily fluid goal. Parents who were concerned about their child's fluid intake were reassured and guided in ways to increase fluid intake without force. Daily fluid totals were examined for each child, allowing for early intervention to prevent dehydration. In the few instances when hydration in the home setting was not maintained, admission to hospital was arranged.

Within 72 hours of surgery, granulation tissue has formed at the surgical site, providing a protective scab over the tonsillar fossae (Kloth et al., 2002). Sloughing of the scab usually occurs two weeks post-tonsillectomy (C. Elliott,

personal communication, November 1, 2002). Therefore, the importance of soft diet for a total of three weeks was stressed to families in order to maintain the integrity of the healing surgical site and to allow sloughing of the protective scab naturally. Premature sloughing of the scab due to rough foods or lack of hydration potentially will lead to increased pain and secondary bleeding. Dependent on group assignment, introduction of dairy products either occurred on the day following surgery, or three days following surgery. It was hypothesized that if dairy products were held until granulation occurred, children would recovery more quickly. Possibly due of lack of statistical power, dairy products were not shown to significantly affect recovery. However, the observed trend supported the research hypothesis and confirmed the need for a fully powered trial.

Seventy-six percent of the children in the study had home humidifiers (76% in the dairy group and 87% in the non-dairy group). As Edmonton has a dry climate, particularly in the winter months, it was hypothesized that children who did not have home humidification in the winter would have more pain. No significant difference in group assignment found during the winter season χ^2 (1) = .038, p = .845 (two-tailed). Visual inspection of the data revealed no difference in pain intensity or incidence of complication based on season of surgery or home humidification. More likely there was a greater impact from oral intake on maintaining hydration of the surgical site and not from home humidification.

Post-operative Health Service Utilization

Throughout the one-year data collection period, field notes were kept documenting information from daily phone calls with families. This information

was invaluable for interpreting trends that were found during the study, such as the increased incidence of otalgia within the dairy group. Parents of children in both groups had access to the primary investigator 24 hours a day and it was not uncommon for parents to phone in the middle of the night, or numerous times in the day if they were concerned about their child.

Of the 36 children enrolled in the study, only 4 (11%) made an unscheduled visit to an outside physician. The first child saw their family physician for otalgia on day 7 and he recommended Motrin®, knowing the child was recovering post-tonsillectomy. Despite the family having received instructions regarding analgesia post-tonsillectomy (no aspirin, no Advil®, no Motrin®, no ibuprofen), they accepted this recommendation. During the daily phone call, this information was elicited, the importance of avoiding blood-thinning products was re-emphasized and the child never received the Motrin®. The second child also saw his family physician with complaints of otalgia and was prescribed an antibiotic for an ear infection on day 10. The third child was seen by an emergency physician on day 4 with complaints of abdominal pain and was sent home without need for treatment. An emergency physician saw the fourth child on day 10 for viral complaints. One child made a scheduled follow up visit with their family physician on day 10 without any complaints noted. Three children, in consultation with the primary investigator and the attending surgeon, were seen in the emergency room and admitted for decreased fluid intake. Of the three children, two were admitted on day 2 and one on day 5.

The literature on morbidity post-tonsillectomy reports much higher rates of general practitioner consultation than the 11% found in this study. Three studies quoted consultation rates of 38.3%, 35%, and 30% (Warnock and Lander, 1998, Wilson, Murray and MacKenzie, 2001 and Bartley and Connew, 1994), while one study reported the consultation rate to be even higher at 60.6% (Lee and Sharp, 1996). Both Warnock and Lander (1998) and Bartley and Connew (1994), had phone follow-up with families. It is unclear if the families had 24-hour access to the researcher, or what their level of expertise was. It is possible that parents who have access to consistent and reliable phone assistance by a nurse practitioner post-tonsillectomy have reduced utilization of health services. Future studies comparing daily phone calls versus pamphlet information post-tonsillectomy to families need to be carried out to determine if this in fact is true.

Nurse Practitioner Support to Caregivers. No other study involving children post-tonsillectomy provided parents with 24-hour access to a nurse practitioner (NP). Despite the prevalence and routine nature of tonsillectomies, a tonsillectomy is still a major surgery, both from a secondary morbidity and family impact perspective. On the surgical day parents are often not able to absorb all of the post-operative information and instructions. Parents in this study were often sleep deprived, as they had to be at the hospital very early in the morning to be registered at day surgery or the pre-admission clinic. Often parents had fasted along with their child and were waiting to eat until their child had gone into the operating room. Depending on number of children that were enrolled in the study on a surgical day, the primary investigator had the opportunity to touch base with

families prior to surgery and to ensure that all their questions had been answered. Often parents were anxious prior to surgery and would say, "I am sure I will have lots of questions after!"

A generalized discharge instruction sheet is handed out to all families post-tonsillectomy prior to discharge. Tonsillectomies are performed by both adult and pediatric otolaryngologists at the study centre, therefore slight variations in post-operative instructions do occur with regards to diet and activity. One of the many advantages of families having access to an NP alleviated some of the pressure of remembering all of the 'rules' post-tonsillectomy. Although post-operative instructions, projected recovery course and expected morbidities are discussed during the pre-operative office visit and prior to discharge, parents often are unable to remember all of this information. The first phone call was made to the family on the surgical evening, once they have had a chance to relax and regain some control in the home setting. This provided time for families to ask any additional questions as well as an opportunity to review all the post-operative instructions and ensure that appropriate medications have been picked up and appropriate fluids are being consumed.

Over the 10-day study period families were able to develop a trust in the NP and felt comfortable enough to phone in the middle of the night if there were concerns with pain, emesis or fluid intake. Some parents continued to call up to four weeks after the surgery if they had additional questions or if their child had "snuck" some rough foods before the allotted three-week timeframe. Stories such as: "He raided the fridge in the middle of the night." or "She had tacos at school

even though she knows she can only have soft food!" were not uncommon. Parents voiced their appreciation through letters at the end of the study in having someone to phone with concerns or questions, "It makes a big difference to be able to talk to someone who can tell you things are normal, especially when it is our children…I don't think you realize how much relief I felt after speaking with you." Consistent NP contact and support enabled children to recover in the home setting with a very low need (11%) compared to the literature for unscheduled physician visits as previously stated (p. 73).

Defining Recovery

For the purpose of this pilot study, strict criteria were set that had to be met prior to a child being considered to have fully recovered post-tonsillectomy. Using these criteria, 75% of the sample did reach a full recovery. Consideration needs to be given to whether or not the criteria for a "successful" recovery should be combined, are they equally weighted? Is the examination of the absence of pain and no further analgesia usage indicative of recovery, or does activity and diet play an important confounding role? Anecdotally, the recovery period post-tonsillectomy can take as long as three weeks. To determine when a full recovery has occurred in this population, a descriptive study needs to be done first to determine the actual timeframe for recovery post-tonsillectomy. Once this timeframe has been established, a fully powered study examining the effect of dairy products on post-tonsillectomy recovery could be undertaken.

Pain Intensities. Multiple studies have examined the relationship between pain and tonsillectomy in children, however information on important variables

such as pre-operative and intra-operative medications associated with decreased pain post tonsillectomy are often not made available to the reader. Warnock and Lander (1998) found that despite instruction on analgesia use, children often do not receive the recommended dose or required frequency of analgesia. Children in this study received documented around the clock analgesia for the first two days and administration continued (often through the night) based on the child's complaints, and in daily consultation with the NP. Acetaminophen dosage was greatest on the 2nd day (dairy average = 5.0, non-dairy average = 4.2) and 3rd day (dairy average = 4.3, non-dairy average = 4.3) following surgery. The dosage levelled off on days four to seven and decreased or ceased on days eight to ten. Pain levels based on the child's own report were highest on the surgical day and followed a downward trajectory for the remainder of the nine days. Both groups documented lower pain than what is cited in the literature (dairy mean score surgery day, post-operative day 1, post-operative day 2 respectively (3.1/10, 3.0/10, 2.7/10) and non-dairy (4.4/10, 4.3/10, 4.1/10). Only those children who had difficulty in meeting the required daily intake or who had complaints of otalgia reported prolonged complaints of pain. Wiggins (2004) found much higher pain intensities for the surgical day (3.3/4.0) and for the two days following surgery (3.3/4.0, 3.1/4.0), when compared to this study. Warnock and Landers (1998) also reported higher pain ratings for the surgical day (66.6/100). Figure 13 compares pain ratings based on a 10-point pain rating scale.

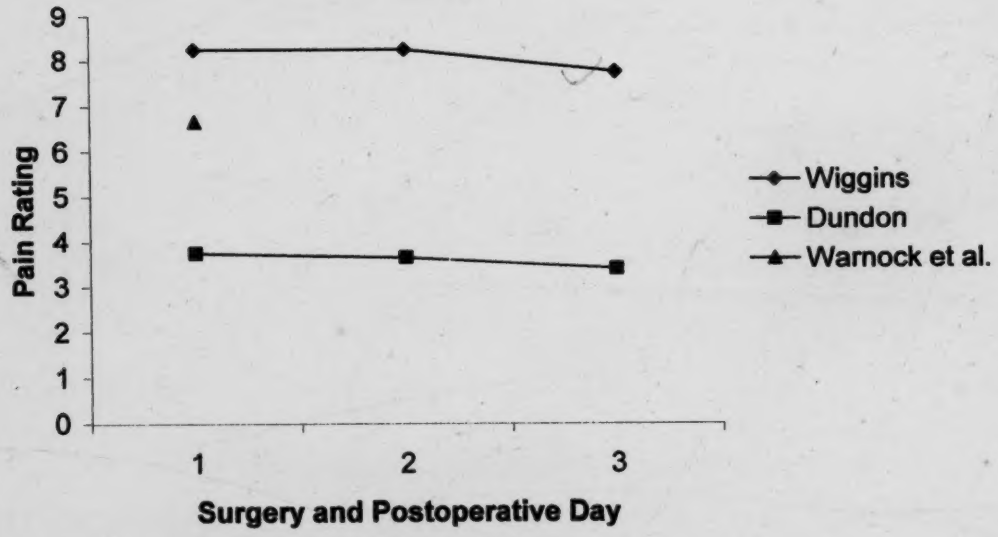

Figure 13. Tonsillectomy Pain Study Comparisons.

Finley et al. (1996) evaluated the prevalence and severity of children's pain at home following 'minor' surgeries, including tonsillectomy. Parents rated their child's 'worse pain' at five appointed time periods on the surgical day and two following days. Parents were also asked to record medications used. More than 25% of the children who had a tonsillectomy still had pain ratings greater than 30 out of 100 on day three (Finley et al., 1996).

Hamers and Abu-Saad (2001) evaluated the prevalence and severity of children's pain at home following adenotonsillectomies. Parents were asked to rate their child's average pain on the surgical day and seven days following surgery. Only mean pain scores for the entire study period were provided. Additionally, parents were interviewed by phone on the 7th day following surgery

regarding their child's complaints of pain; sleep disturbances, difficulties with foods and fluids and secondary morbidities (Hamers et al., 2001).

Analgesia Usage. The importance of routine acetaminophen administration was stressed to parents post-tonsillectomy. A number tonsillectomy studies have found that despite instruction on analgesia use, child are under medicated. Finley et al., (1996) asked parents to respond to six attitudinal statements concerning children's pain medication post-tonsillectomy. Although 80% of parents agreed that acetaminophen could be used without much worry, parents were still hesitant to use medications; 42% of the parents stating that pain medication should be used as last resort (Finley et al., 1996). Similarly, Hamers et al., (2001) found that although parents stated that their child had suffered at home following surgery only 51% of them administered paracetamol at regular intervals. Unfortunately this finding is consistent in the literature regarding the home management of pain post-tonsillectomy. Routine dosing of acetaminophen in this study, with adequate fluid intake, potentially resulted in the documented low pain intensities.

Diet. Maintaining the child's diet history over the 10-day period was a lot of work for parents. Although an onerous task, it provided beneficial information on: determining when toleration of soft diet occurred, relation of diet to pain intensity and co-morbidity, in particular secondary haemorrhage. No adaptation of the diet history would need to be done for future study.

Activity. Numerous tonsillectomy studies considered a child to be recovered based on activity, yet no definitions or criteria were provided to the

reader. As no activity scales were available for the child recovering from a tonsillectomy, one was designed for the purpose of the study. A child was thought to have regained a normal level of activity when he or she could play independently. Activity was measured on a four point ordinal scale. In level one, the least active, the child was lying on the couch or bed doing nothing. In level two the child was sitting on the couch or bed, engaged in some quiet activity. In level three the child was playing independently. In level four the child had returned to day-care or school. Activity levels were measured with very acetaminophen dose.

When a child no longer required acetaminophen, then the activity level was measured once a day, preferably at the same time of day. For the first 2 days, acetaminophen dosing was every four hours, around the clock. This meant that activity levels were being measured when the child had been asleep and was merely woken for an acetaminophen dose.

For future use, it would make more sense to measure activity levels only during waking hours. To better capture the true activity of a child post-tonsillectomy, various revisions would need to be made. Level one might reflect quiet activity in the immediate post-operative period, such as watching movies or cartoons. Level two might reflect more independent play. Level three might reflect a return to "normal personality or back to "old self." Finally, level four would reflect a return to school/daycare depending on the child's age. Appropriate testing to determine the specificity and sensitivity of this scale would be required.

Future study will enable further development and validation of an activity scale that it more reflective of a child's expected activity level post-tonsillectomy.

Study Limitations and Recommendations for Future Study

The primary limitation of this study was the lack of power. In order to increase the internal validity of the study to control for confounders, children were recruited from only one pediatric otolaryngologist. Based on strict inclusion and exclusion criteria 46 children were eligible for enrollment over a one-year period. One family declined participation, for a total of 45 enrolled children. Return of complete data yielded a total sample size of 36.

When significance is not found in a study, power needs to be re-examined. One goal of this pilot study was to estimate effect size so that reliable sample size calculations could be determined for a fully powered randomized control trial. For future a fully powered randomized control trial, with a power of 0.8 and α of 0.05, 62 children would need to be recruited per group for a moderate effect size (0.50), or 392 children recruited per group for small effect size (0.20) (Polit, pg. 139, 1996). For future study, consideration needs to be given to two interventions: dairy products and nurse practitioner support. Detailed sample size calculations can be found in Appendix F.

To fully understand post-tonsillectomy recovery in the family context, future studies should include demographic variables such as the distance the family has travelled for pre-operative consultations and surgery, any financial hardships such as those associated with hotel stays and food expenditures, as well as time required away from work to care for a child post-tonsillectomy. As

previously mentioned (p. 79), the activity scale would need to be redesigned and validated for the pediatric tonsillectomy population.

This study suggests that a pediatric otolaryngology NP may have important positive effects on the recovery process of children post-tonsillectomy. Although the original intent of an NP phoning families every day for the 10-day study period was to maximize response rates, the positive impact of 24-hour access to an NP on children's recovery was quickly evident. Future studies need to compare recovery rates and unscheduled physician visits between groups that have access to an NP or only to information supplied in the form of a pamphlet.

Appendix A

Demographic Data

Study ID Number_____

Reason for Surgical Procedure_____

Date of Surgery_____

Surgical Procedure_____

Date of Birth_____

Sex Of Child_____

Weight_____kg

Humidifier In Home_____Yes/No

Day Dairy Started_____

Day Soft Diet Tolerated_____

Ethnicity_____

Faces Pain Scale – Revised (FPS-R)

In the following instructions, say "hurt" or "pain," whichever seems right for a particular child.

"These faces show how much something can hurt. This face *[point to left-most face]* **shows no pain. The faces show more and more pain** *[point to each from left to right]* **up to this one** *[point to right-most face]* **– it shows very much pain. Point to the face that shows how much you hurt** [right now]**."**

Score the chosen face 0, 2, 4, 6, 8, or 10, counting left to right, so '0' = 'no pain' and '10' = 'very much pain.'
Do not use words like 'happy' and 'sad'. This scale is intended to measure how children feel inside, not how their face looks.

Hicks CL, von Baeyer CL, Spafford P, van Korlaar I, Goodenough B. The Faces Pain Scale – Revised: Toward a common metric in pediatric pain measurement. *Pain* 2001;93:173-183.
Scale adapted from: Bieri D, Reeve R, Champion GD, Addicoat L, Ziegler J. The Faces Pain Scale for the self-assessment of the severity of pain experienced by children: Development, initia validation and preliminary investigation for ratio scale properties. *Pain* 1990;41:139-150.

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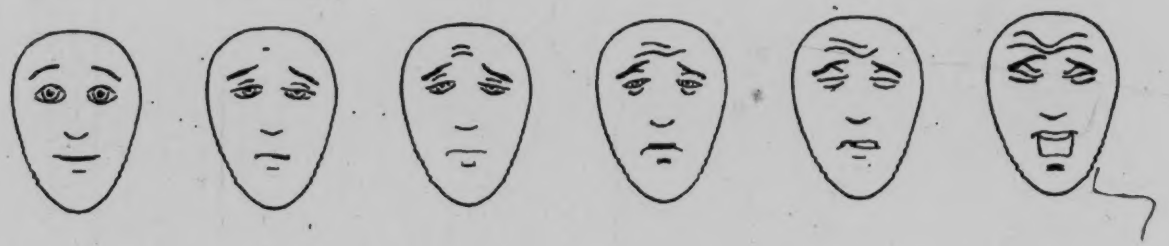
Version: 24 Sep 2001

FPS-R

Fold here

0 2 4 6 8 10



How to Reach Us:

Belinda Dundon

Pager	(780) 445-6485
Office/Voice Mail	(780) 407-7726
Lynne Ray	
Office	(780) 492-7558
Dr. C. Elliott	
Office	(780) 432-0120

Please feel free to contact us if you have any questions.

Thank you.

Belinda Dundon

If you have Concerns:

If you have any concerns about any aspect of this study, you may contact the Patient Concerns Office at the Capital Health Authority at 407-1040. This office has no affiliation with study investigators.

The Effect of Dairy Products On Post-Tonsillectomy Recovery

We are doing a study to find out if dairy products affect the recovery period after a tonsillectomy.

Information Pamphlet

Appendix C

The Effect of Dairy Products On Post-Tonsillectomy Recovery

Researchers:

Belinda Dundon, RN, Masters Student
Faculty of Nursing, University of Alberta

Lynne Ray, RN Ph.D. Assistant Professor, Faculty of Nursing, University of Alberta

Nicole Letourneau, RN Ph.D. Assistant Professor, Faculty of Nursing, University of Alberta

Dr. Clark Elliott, MD Pediatric Otolaryngologist, Stollery Children's Hospital

Purpose of this Study

Your child is going to have a tonsillectomy. You are being asked if you and your child will take part in a study. We want to find out if not eating or drinking dairy for three days will help your child recover faster. By dairy we mean milk, cheese, pudding, yoghurt and soya. There is no research that tells us if dairy makes a difference to recovery. That is why we are doing the study.

What will Happen

If you take part in this study, Belinda will meet you in Day Ward after your child's surgery. She will tell you if your child is going to be in the dairy or non-dairy group. The dairy group will eat the usual hospital tonsil diet. This diet includes lots to drink and soft foods for 3 weeks. The non-dairy group cannot have milk, cheese pudding, yoghurt, ice cream or soya for the first 3 days. After 3 days they can eat and drink dairy. Your child has an equal chance of being in the dairy or non-dairy group. This will happen by chance, much like flipping a coin.

When you go home you will need to write down everything your child eats and drinks for 10 days. You will also be asking your child if she/he has any pain. You will be taught how to use a pain rating scale. You will ask about your child's pain 6 times a day for the first 3 days. Then you will ask about any pain at least once a day for 7 more days. You will write down if you child has any of the following problems: upset tummy, throws up, won't drink, or has any fresh blood from his/her mouth. You will also write down how active your child is. Writing down this information will take about 20 minutes each day for 10 days.

When Belinda meets you in the Day Ward she will explain your child's diet. She will also give you the forms to write down what your child eats and drinks. The form also has room to check off the possible problems, the pain level, and how active your child is.

After you go home, Belinda will call you every day for ten days to see how you and your child are doing.

Dr. Elliott will not know if you chose to be part of the study or not. If you need to talk to Dr. Elliott about your child's progress after surgery, you will need to tell him that you are in the study and which diet you child is on.

It's Your Choice

It is your choice whether you and your child take part in this study. We think that if your child does not have dairy products, he/she may recover more quickly. We do not know this for sure. We do not believe there are any risks to taking part in this study.

You are free to withdraw your child from this study at any time. You do not have to answer any questions that you do not want to. Taking part in this study, or dropping out, will not affect the care provided to your child.

How We will Use the Information

All information will be held private except when professional codes of ethics or legislation require reporting. We will use a code number on data sheets instead of your child's name. The data will be stored in a secure place for 5 years. Only the study team will have access to the data. We will seek ethics approval if we use the data for further study. The findings of this study may be published or presented at conferences. No information will be published that could identify your child.

Appendix D

Consent Form

The effect of dairy products on post-tonsillectomy recovery.

Consent Form

Part 1: Researcher Information			
Principal Investigator	**Affiliation**	**Contact Information**	
Belinda Dundon	University of Alberta, Faculty of Nursing	bdundon@cha.ab.ca	407-7726
Co-Investigators	**Affiliation**	**Contact Information**	
Lynne Ray	University of Alberta, Faculty of Nursing	Lynne.Ray@ualberta.ca	492-7558
Nicole Letourneau	University of Alberta, Faculty of Nursing	Nicole.Letourneau@ualberta.ca	492-1121
Clark Elliott	Pediatric Surgery, Stollery Children's Hospital	pedoto@mac.com	432-0120

Part 2: Consent of Participant	Yes	No
Do you understand that you have been asked to be in a research study?		
Have you read and received a copy of the attached information sheet?		
Do you understand the benefits and risks involved in taking part in this research study?		
Have you had an opportunity to ask questions and discuss the study?		
Do you understand that you are free to refuse to participate or withdraw from the study at any time? You do not have to give a reason and it will not affect your child's care.		
Has the issue of confidentiality been explained to you? Do you understand who will have access to your records/information?		

Part 3: Signatures

This study was explained to me by: _____

Date: _____

I agree to take part in this study.

Signature of Research Participant: _____

Printed Name: _____

Witness (if available): _____

Printed Name: _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Researcher: _____

Printed Name: _____

* A copy of this consent form must be given to the participant.

The effect of dairy products on post-tonsillectomy recovery

By: Belinda Dundon, Lynne Ray, Nicole Letourneau, and Dr. Elliott

Kids' Assent Form

You are going to come to the hospital to have your throat fixed. After you go home you will have lots to drink. We want to find out if some food and drinks make kids throats get better faster. We are doing an experiment to find this out.

Kids who want to be part of the experiment will be in two groups. Kids in Group 1 will have things with milk as soon as they go home. Kids in Group 2 will not have milk for three days. You will find out when you come to the hospital if you are on the milk team or juice team.

When you get home your mom or dad will write down what you eat and drink. They will also ask you how you are feeling every day. They will have a special sheet to write down what you eat and drink and how you feel. Your mom or dad will do this for 10 days. Then they will mail the sheet to Belinda. Belinda will call every day to see how you are doing

Belinda answered my questions Yes_____ No_____

Do you want to be a part of this experiment? Yes_____ No_____

_____ _____

Kid's name Belinda's signature

Appendix E

Data Table

Day:_____

	Food and Fluid	Amount	Complications (label each time they happen)
Morning			
Afternoon			
Evening			

Time Tylenol Given _____mg	Activity Level	Pain Score (0-10)

Complications
N = nausea
V = vomiting
D = dehydration
B = bleeding

Activity Levels
1= lying on couch or bed (doing little)
2= sitting on couch or bed (quiet)
3= playing by own
4= return to school/child care

Appendix F

Detailed Sample Size Calculations

$$\Delta = \text{effect size} \sqrt{\frac{n}{2}}$$

$\Delta = 2.8$

moderate effect size = 0.50

small effect size = 0.20

$\alpha = 0.5$

power = 0.80

Therefore, $n = 62$ per group for a moderate effect size and $n = 392$ per group for small effect size.

Appendix G

Ethical Approval

Health Research Ethics Board

2J2.27 Walter Mackenzie Centre
University of Alberta, Edmonton, Alberta T
p.780.492.9724
p.780.492.0459
f.780.492.7303
ethics@med.ualberta.ca

UNIVERSITY OF ALBERTA HEALTH SCIENCES FACULTIES, CAPITAL HEALTH AUTHORITY, AND CARITAS HEALTH GROUP

HEALTH RESEARCH ETHICS APPROVAL

Date of HREB Meeting:	February 7, 2003
Name of Applicant:	Belinda Dundon & Dr. Lynne Ray
Organization:	CHA/University of Alberta
Department:	Stollery Children's Hospital/Faculty of Nursing
Project Title:	**The effect of dairy products on post-tonsillectomy recovery**

The Health Research Ethics Board (HREB) has reviewed the protocol for this project and found it to be acceptable within the limitations of human experimentation. The HREB has also reviewed and approved the subject information letter and consent form, if applicable.

The approval for the study as presented is valid for one year. It may be extended following completion of the yearly report form. Any proposed changes to the study must be submitted to the Health Research Ethics Board for approval. Written notification must be sent to the HREB when the project is complete or terminated.

Sharon Warren

Dr. Sharon Warren
Chair of the Health Research Ethics Board
(B: Health Research)

File number: B-030203-CHA

Appendix H

Letter of Support

January 20, 2003

Dear Ishrat Bhatti,
Health Research Ethics Board: Panel B
3-48 Corbett Hall
University of Alberta
Edmonton, AB T6G 2G4

RE: The Effect of Dairy Products o Post-Tonsillectomy Recovery

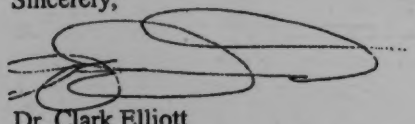
I am writing this letter in support of Belinda Dundon recruiting patients consented for tonsillectomy surgery from my office.

I understand that the project would involve enrolling 30 families who will have a child adm to Stollery for tonsillectomy day surgery. The families will be identified in my office, once surgical consent has been obtained. Belinda Dundon has outlined inclusion/exclusion criter that appropriate families can be identified for the study.

The process has been established so that I, Dr. Elliott, will not know the identity of the fam recruited. Belinda Dundon, the primary investigator, will be the only person who knows the families' identities.

I believe that this study will help determine whether children who are withheld from dairy products have a shorter recovery period, and look forward to hearing the results of the stud

Sincerely,



Dr. Clark Elliott
Pediatric Surgery, Otolaryngology

Capital Health

Healthier people in healthier communities

University of Alberta Hospital

8440 – 112 Street
Edmonton, Alberta
Canada T6G 2B7
Phone: (780) 407-8822

February 24, 2003

Shanie Maharaj
CHA Regional Research Administration
The Northern Alberta Clinical Trials & Research Centre
Ste 1800 College Plaza
Edmonton, AB T6G 2B7

Re: Effect of Dairy Products on Post Tonsillectomy Patients

Dear Ms. Maharaj

Belinda Dundon has reviewed the protocol for this study with me. We have agreed that Dayward will be impacted in the following ways:

- Between March 1, 2003 and the end of May, the investigator plans to enroll 2-3 patients per week for a total of 40 patients.
- The surgeon's office will assess the suitability of patients to participate in the study and will work with the investigator to obtain consent. A list of patients who are enrolled in the study will be provided to Dayward and a copy of the study consent will be appended to the Day Surgery chart.
- Patients will be randomized into treatment groups by the dietician. She will also provide postoperative diet instructions to all patients enrolled in the study - regardless of group assignment. Dayward nurses will provide all other postoperative teaching.

Thank you for the opportunity to review this protocol and to work with the investigator to determine parameters that will allow us to meet our patient care commitments and support this research endeavor. I look forward to working with Belinda and wish her every success in completing her project.

Sincerely,

C Gerdes.

Cindy Gerdes, RN MN
Unit Manager
Dayward, Pre-Admission Clinic, Same Day Admit Unit
24 Hour Unit, Pain Clinic & Otolaryngology Clinic

cc. Belinda Dundon

3045374

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